

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,)
) CR-18-00258-EJD
 PLAINTIFF,)
) SAN JOSE, CALIFORNIA
 VS.)
) MAY 5, 2021
 ELIZABETH A. HOLMES,)
) PAGES 1 - 156
 DEFENDANT.)
 _____)
)

TRANSCRIPT OF PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF: UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
JEFFREY B. SCHENK
150 ALMADEN BOULEVARD, SUITE 900
SAN JOSE, CALIFORNIA 95113

BY: ROBERT S. LEACH
KELLY VOLKAR
1301 CLAY STREET, SUITE 340S
OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTERS:

IRENE L. RODRIGUEZ, CSR, RMR, CRR
CERTIFICATE NUMBER 8074
LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

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A P P E A R A N C E S: (CONT'D)

FOR DEFENDANT HOLMES: WILLIAMS & CONNOLLY LLP
BY: KEVIN M. DOWNEY
LANCE A. WADE
PATRICK LOOBY
KATHERINE TREFZ
AMY SAHARIA
J.R. FLEURMONT
SEEMA ROPER
725 TWELFTH STREET, N.W.
WASHINGTON, D.C. 20005

1 SAN JOSE, CALIFORNIA

MAY 5, 2021

2 P R O C E E D I N G S

08:48AM 3 (COURT CONVENED AT 9:04 A.M.)

09:04AM 4 THE COURT: ALL RIGHT. LET'S GO BACK ON THE RECORD
09:04AM 5 IN 18-258, UNITED STATES VERSUS ELIZABETH HOLMES.

09:04AM 6 I SEE ALL COUNSEL PRESENT. MS. HOLMES IS PRESENT. WE'RE
09:04AM 7 READY TO PROCEED WITH OUR MOTIONS IN LIMINE.

09:04AM 8 FOR WEDNESDAY I THINK OUR SCHEDULE SHOWS, OR THE SCHEDULE
09:04AM 9 I HAVE SHOWS THE FIRST MOTION UP IS GOVERNMENT'S MOTION IN
09:05AM 10 LIMINE NUMBER 4 REGARDING CHARGING DECISIONS. I THINK THAT'S
09:05AM 11 WHAT IS UP.

09:05AM 12 BUT BEFORE WE TAKE THAT UP, ANYTHING EITHER COUNSEL WANTS
09:05AM 13 TO INDICATE FOR THE RECORD BEFORE WE START?

09:05AM 14 MR. SCHENK: NOTHING FROM THE GOVERNMENT. THANK
09:05AM 15 YOU.

09:05AM 16 MS. SAHARIA: NOTHING, YOUR HONOR.

09:05AM 17 I WOULD JUST NOTE WE HAVE A NEW MEMBER OF OUR TEAM HERE
09:05AM 18 TODAY, PATRICK LOOBY, WHO YOU HAVE MET BY ZOOM BUT NOT IN
09:05AM 19 PERSON.

09:05AM 20 THE COURT: GOOD MORNING. NICE TO SEE YOU.

09:05AM 21 MR. LOOBY: GOOD MORNING.

09:05AM 22 THE COURT: ALBEIT THROUGH THE PLEXIGLASS. IT'S
09:05AM 23 NICE TO SEE YOU. I'M SURE WE ALL LOOK VERY DIFFERENT ON THE
09:05AM 24 OTHER SIDE OF THE PLEXIGLASS.

09:05AM 25 LET'S SEE. MR. SCHENK, ARE YOU RISING TO THIS MOTION?

09:05AM 1 MR. SCHENK: YES. THANK YOU, YOUR HONOR.

09:05AM 2 GOOD MORNING AGAIN. JEFF SCHENK FOR THE UNITED STATES.

09:05AM 3 YOUR HONOR, I THINK THIS MOTION, THE GOVERNMENT'S 4TH

09:05AM 4 MOTION IN LIMINE, MAY FIT INTO THE CATEGORY OF THE ONES THAT WE

09:05AM 5 CAN DEAL WITH QUICKLY.

09:05AM 6 THE COURT WILL RECALL THAT IN THIS MOTION THE GOVERNMENT

09:05AM 7 IS SEEKING TO PRECLUDE ARGUMENTS FROM THE DEFENSE THAT ALLEGE

09:06AM 8 THAT THE CHARGING DECISIONS IN THIS CASE WERE BASED ON SOME

09:06AM 9 COORDINATION THAT, FRANKLY, DID NOT OCCUR BETWEEN THE

09:06AM 10 GOVERNMENT AND EITHER JOURNALISTS OR COMPETING LAB COMPANIES.

09:06AM 11 THE COURT KNOWS THAT DURING THE DOWNFALL OF THERANOS THERE

09:06AM 12 WERE STATEMENTS FROM MS. HOLMES AND OTHERS AT THERANOS THAT THE

09:06AM 13 RESPONSE TO THE MEDIA WAS BECAUSE OF MISGUIDED JOURNALISM OR

09:06AM 14 BECAUSE OF STORIES PLANTED BY COMPETING LAB COMPANIES.

09:06AM 15 SO THE GOVERNMENT IS EXPRESSING CONCERN WITH THOSE SAME

09:06AM 16 THEORIES. THEY ARE GOING TO INFECT THIS TRIAL, AND THERE IS

09:06AM 17 JUST NO BASIS FOR. THE U.S. ATTORNEY'S OFFICE, THE CRIMINAL

09:06AM 18 INVESTIGATORS DID NOT COORDINATE WITH JOURNALISTS, DID NOT

09:06AM 19 COORDINATE WITH LAB COMPANIES. AND TO MAKE THOSE ARGUMENTS TO

09:06AM 20 THE JURY WOULD BE MAKING ARGUMENTS THAT SIMPLY ARE NOT TRUE.

09:06AM 21 THE DEFENSE IN RESPONSE SAYS THE LIMITS OF THE

09:06AM 22 GOVERNMENT'S STATEMENTS TO THE COURT ARE TELLING. THAT IS, THE

09:07AM 23 GOVERNMENT'S STATEMENTS IN ITS MOTION WERE THAT THE PROSECUTION

09:07AM 24 AND THE CRIMINAL INVESTIGATORS DID NOT COORDINATE WITH LAB

09:07AM 25 COMPANIES OR WITH JOURNALISTS.

09:07AM 1 BUT IF YOU GO BACK FURTHER IN TIME, CMS SPOKE TO
09:07AM 2 JOURNALISTS, THERE WERE OTHER INTERVIEWS CONDUCTED OF LAB
09:07AM 3 COMPANIES, AND THAT THEY SHOULD BE ALLOWED TO MAKE THESE KIND
09:07AM 4 OF COORDINATION OR CHARGING DECISION-BASED ARGUMENTS.

09:07AM 5 I THINK AT FIRST IT WOULD BE HELPFUL FOR THE COURT TO JUST
09:07AM 6 KNOW IF THE DEFENSE PLANS TO MAKE THOSE ARGUMENTS. IS IT,
09:07AM 7 HYPOTHETICALLY SPEAKING, WE SHOULD BE ALLOWED TO MAKE THEM:
09:07AM 8 OR, NO, JUDGE, YOU SHOULD DENY THE MOTION BECAUSE WE DO INTEND
09:07AM 9 TO AND THIS IS RIGHT.

09:07AM 10 I THINK THAT WOULD BE ILLUMINATING BECAUSE THERE MAY NOT
09:07AM 11 BE A CONTROVERSY FOR THE TO DECIDE IF THE DEFENSE DOES NOT
09:07AM 12 INTEND TO MAKE THOSE ARGUMENTS.

09:08AM 13 MOREOVER, IF THEY DO, THE COURT SHOULD PREVENT THEM. THE
09:08AM 14 LINE OF CASES THAT THE DEFENSE CITES SUGGESTING THAT IT WOULD
09:08AM 15 BE APPROPRIATE TO MAKE THOSE ARGUMENTS ALL SPEAK TO IMPROPER
09:08AM 16 LIMITATIONS THAT THE COURT PLACED ON, FOR EXAMPLE,
09:08AM 17 CROSS-EXAMINATION OF AN AGENT ON THE STAND.

09:08AM 18 WHEN A DEFENSE ATTORNEY WANTED TO CALL INTO QUESTION THE
09:08AM 19 STRENGTH OF THE GOVERNMENT'S INVESTIGATION, A COURT INTERRUPTED
09:08AM 20 AND TOLD THE JURY, YOU'RE HERE TO GRADE THE PRODUCT OF THE
09:08AM 21 INVESTIGATION, THE EVIDENCE, NOT THE CONDUCT OF THE
09:08AM 22 INVESTIGATION, AND THE REVIEWING COURT SAID, NO, THAT'S NOT
09:08AM 23 APPROPRIATE, YOU CAN'T REALLY REVIEW ONE WITHOUT THE OTHER.

09:08AM 24 AND THAT ISN'T WHAT WOULD OCCUR HERE IF THE COURT
09:08AM 25 PRECLUDED THE DEFENSE FROM GOING INTO PRECRIMINAL INVESTIGATION

09:08AM 1 ALLEGED COORDINATION, AND THAT'S AN IMPORTANT DISTINCTION
09:08AM 2 BECAUSE THE GOVERNMENT'S CHARGING DECISIONS IN THIS CASE WERE
09:08AM 3 NOT, AND THE DEFENSE DOES NOT ALLEGE WERE, INFLUENCED BY
09:08AM 4 COORDINATION BETWEEN THE U.S. ATTORNEY'S OFFICE, THE
09:08AM 5 PROSECUTORS IN THE CASE, THE CRIMINAL INVESTORS --
09:09AM 6 INVESTIGATORS IN THE CASE, AND THE LAB INDUSTRY AND THE
09:09AM 7 JOURNALISTS, AND THAT'S AN IMPORTANT DISTINCTION BECAUSE THAT'S
09:09AM 8 ONE THAT IS NOT ASSUMED WITHIN THE CASE LAW THAT SAYS BROAD
09:09AM 9 DISCRETION TO ATTACK THE STRENGTH OF THE CRIMINAL
09:09AM 10 INVESTIGATION.

09:09AM 11 SO THE -- GRANTING THE MOTION WOULD NOT RUN AFOUL OF THOSE
09:09AM 12 CASES, AND IT REALLY SUGGESTS IF THE DEFENSE MAKES THOSE
09:09AM 13 ARGUMENTS THAT COORDINATION EXISTS WHERE IT REALLY DID NOT.

09:09AM 14 AGAIN, THIS IS JUST SORT OF A MOTION BASED ON ARGUE WHAT
09:09AM 15 THE FACTS ARE AND DON'T MISLEAD THE JURY.

09:09AM 16 THANK YOU.

09:09AM 17 THE COURT: OKAY. THANK YOU.

09:09AM 18 MR. WADE.

09:09AM 19 MR. WADE: GOOD MORNING, YOUR HONOR. LANCE WADE ON
09:09AM 20 BEHALF OF MS. HOLMES.

09:09AM 21 WE DO NOT INTEND TO ARGUE THAT THE GOVERNMENT CHARGING
09:09AM 22 DECISION WAS EXECUTED IN COORDINATION WITH JOURNALISTS OR
09:09AM 23 COMPETITORS, THAT IS TO SAY THAT THESE PROSECUTORS, YOU KNOW,
09:09AM 24 GOT IN A ROOM AND REACHED SOME AGREEMENT.

09:10AM 25 INTERACTIONS BETWEEN JOURNALISTS AND COMPETITORS AND OTHER

09:10AM 1 GOVERNMENT REGULATORS COULD BE RELEVANT IN THE CASE. I
09:10AM 2 RECOGNIZE MR. SCHENK'S INVITATION TO PREVIEW ALL OF THE
09:10AM 3 EVIDENCE THAT WE WANT TO OFFER IN OUR DEFENSE.

09:10AM 4 THE COURT: DO YOU WANT TO ACCEPT THAT INVITATION?

09:10AM 5 MR. WADE: I'LL DECLINE THE INVITATION.

09:10AM 6 BUT SUFFICE IT TO SAY THAT THERE ARE WAYS IN WHICH CMS
09:10AM 7 WITNESSES, FDA WITNESSES, AND OTHERS WERE IN CONTACT WITH
09:10AM 8 COMPETITORS AND JOURNALISTS DURING KEY TIME PERIODS THAT COULD
09:10AM 9 WELL GO -- BE APPROPRIATE CROSS-EXAMINATION OF WITNESSES WHO
09:10AM 10 ARE CALLED TO TESTIFY IN THE CASE.

09:10AM 11 THEORETICALLY THERE COULD BE CROSS-EXAMINATION OF
09:10AM 12 GOVERNMENT INVESTIGATING AGENTS IF THERE'S SOME INDICATION THAT
09:10AM 13 THE INVESTIGATING AGENT ONLY PURSUED CERTAIN INVESTIGATION
09:10AM 14 BECAUSE IT WAS WHAT WAS REPORTED IN THE MEDIA AND DIDN'T PURSUE
09:10AM 15 OTHER INVESTIGATION, FOR EXAMPLE.

09:11AM 16 BUT THIS IS ALL IN THE CATEGORY OF EVIDENCE-SPECIFIC
09:11AM 17 ISSUES THAT SHOULD BE DEFERRED AND DEALT WITH AS WE DEAL WITH
09:11AM 18 EVIDENCE AT TRIAL. WE'VE POINTED TO THIS EVIDENCE AS EXAMPLES
09:11AM 19 WITHIN OUR BRIEFING.

09:11AM 20 MR. LOOBY WILL ARGUE THE CMS MOTION LATER TODAY. I THINK
09:11AM 21 YOU'LL SEE IN THAT MOTION THAT THERE IS SOME INDICATION THAT
09:11AM 22 THE CMS ACTED DIFFERENTLY AS A RESULT OF INQUIRIES FROM
09:11AM 23 JOURNALISTS AND THEY IMPOSED DIFFERENT PROCEDURES.

09:11AM 24 EVIDENCE OF THAT KIND IS PERFECTLY RELEVANT IN THIS CASE
09:11AM 25 IN TERMS OF QUESTIONING THE WITNESS WHO TALKS ABOUT THE

09:11AM 1 PROCEDURES THAT THEY DID DURING AN INSPECTION IF THAT EVIDENCE
09:11AM 2 COMES IN. IT MAY NOT COME IN. IT PROBABLY SHOULDN'T COME IN.
09:11AM 3 BUT IF IT DOES, THAT CROSS-EXAMINATION IS CLEARLY RELEVANT
09:11AM 4 AND --

09:11AM 5 THE COURT: PARDON ME FOR INTERRUPTING YOU.
09:12AM 6 YOU'RE TALKING ABOUT, FOR EXAMPLE, THE CALIFORNIA
09:12AM 7 DEPARTMENT OF PUBLIC HEALTH TYPICALLY DOES A CERTAIN TYPE OF
09:12AM 8 INVESTIGATION, BUT IN THIS CASE ANOTHER FEDERAL AGENCY DECIDED
09:12AM 9 TO DO IT ON THEIR OWN AND YOU SHOULD BE ABLE TO, IF THAT
09:12AM 10 EVIDENCE IS PERMITTED, YOU SHOULD BE ABLE TO INQUIRE ABOUT WHY
09:12AM 11 THAT DISTINCTION WAS MADE. IT'S -- IS THAT WHAT YOU'RE TALKING
09:12AM 12 ABOUT?

09:12AM 13 MR. WADE: THAT IS AN EXAMPLE, YOUR HONOR.
09:12AM 14 AND THAT WITNESS HAS SAID ESSENTIALLY THAT IT WAS MADE
09:12AM 15 BECAUSE IT HAD A HEIGHTENED PROFILE, BECAUSE IT WAS IN THE
09:12AM 16 MEDIA AND THEY WERE GETTING INQUIRIES FROM JOURNALISTS IN THAT
09:12AM 17 TIME PERIOD.

09:12AM 18 THERE ARE OTHER WITNESSES WHO SUGGESTS THAT THERE WERE
09:12AM 19 DOCUMENTS FROM CMS THAT SUGGEST THAT MAYBE THERANOS WAS BEING
09:12AM 20 TREATED DIFFERENTLY BECAUSE OF THE SOME OF THE MEDIA INQUIRIES.

09:12AM 21 AGAIN, I DON'T --

09:12AM 22 THE COURT: SO DO YOU HAVE -- IS THERE GOING TO BE
09:12AM 23 EVIDENCE, TO THE EXTENT THAT YOU CAN TELL ME NOW, IS THERE
09:12AM 24 EVIDENCE THAT THE GOVERNMENT COORDINATED WITH JOURNALISTS TO DO
09:13AM 25 THIS INVESTIGATION? -

09:13AM 1 MR. WADE: BY "GOVERNMENT" YOU MEAN THE PROSECUTORS
09:13AM 2 WHO ARE INVOLVED IN THIS CASE, THE DEPARTMENT OF JUSTICE
09:13AM 3 PROSECUTORS?

09:13AM 4 THE COURT: WELL, LET'S START THERE AND WORK OUR WAY
09:13AM 5 DOWN.

09:13AM 6 MR. WADE: I HAVE NOT SEEN EVIDENCE THAT THEY HAVE
09:13AM 7 COORDINATED AND WOULD NOT INTEND TO ARGUE THAT THEY COORDINATED
09:13AM 8 AS SUCH.

09:13AM 9 AND TO THE EXTENT THAT YOU LOOK AT THE TITLE OF THE
09:13AM 10 GOVERNMENT'S MOTION, COORDINATION WITH RESPECT TO CHARGING
09:13AM 11 DECISIONS, WE CAN LIVE WITH AN ORDER ON THAT.

09:13AM 12 BUT THE BODY OF THEIR ARGUMENT TRIES TO CREEP A LITTLE BIT
09:13AM 13 MORE INTO CROSS-EXAMINATION THAT GOES TO MOTIVE FOR CERTAIN
09:13AM 14 ACTIONS AND THINGS THAT THE GOVERNMENT MAY CHOOSE TO BRING INTO
09:13AM 15 THIS CASE. IF THEY CHOOSE TO BRING IT INTO THE CASE, WE GET TO
09:13AM 16 CROSS-EXAMINE THE WITNESSES.

09:13AM 17 THE COURT: I THINK EVERYONE RECOGNIZES THAT THE
09:13AM 18 DEFENSE WILL HAVE AN OPPORTUNITY, AND SHOULD, TO CRITICIZE THE
09:13AM 19 DEFENSE -- OR CRITICIZE THE PROSECUTION. YOU HAVE AN ABSOLUTE
09:13AM 20 RIGHT TO CRITICIZE THE EVIDENCE THAT IS PRESENTED OF AND TEST
09:13AM 21 THE EVIDENCE. THAT'S THE JURY PROCESS.

09:14AM 22 YOU HAVE THE RIGHT TO DO THAT.

09:14AM 23 I THINK WHAT THIS MOTION SPEAKS TO IS YOU CAN'T CREATE
09:14AM 24 SOMETHING THAT DOESN'T EXIST, AND THE COORDINATION, I THINK,
09:14AM 25 THAT MR. SCHENK SPEAKS TO IS -- AND THIS IS PROPHYLACTIC, I

09:14AM 1 THINK, FROM THE GOVERNMENT'S PERSPECTIVE. THERE'S FEAR THAT
09:14AM 2 PERHAPS THE DEFENSE MIGHT SAY THAT THE ONLY REASON THIS CASE
09:14AM 3 WAS PROSECUTED IN THE WAY THAT IT WAS IS BECAUSE CERTAIN
09:14AM 4 JOURNALISTS, CERTAIN NEWS ARTICLES, CERTAIN MEDIA DECIDED TO
09:14AM 5 GUIDE THE PROSECUTION AND BUT FOR THAT OR IN ANY OTHER CASE
09:14AM 6 THAT WOULDN'T HAVE HAPPENED.

09:14AM 7 IS THAT FAIR, MR. SCHENK?

09:14AM 8 MR. SCHENK: YES. PRECISELY. THANK YOU.

09:14AM 9 MR. WADE: WE CERTAINLY DON'T INTEND TO CREATE
09:14AM 10 EVIDENCE WHERE NONE EXISTS AND TO CREATE ARGUMENTS THAT ARE NOT
09:14AM 11 BASED ON EVIDENCE. THAT WOULD BE IMPROPER AS THE COURT KNOWS
09:14AM 12 AND AS COUNSEL WELL KNOWS.

09:14AM 13 SO WE'RE MINDFUL OF THAT LINE AND DON'T INTEND TO CROSS
09:14AM 14 IT. WE'LL SEE WHERE THE EVIDENCE GOES BASED ON WHAT THE
09:15AM 15 GOVERNMENT OFFERS AND BASED ON WHAT WE SEEK TO PUT ON, AND IF
09:15AM 16 MEDIA OR COMPETITORS OR INTERACTIONS ARE RELEVANT WITH
09:15AM 17 WITNESSES, WE'LL DRAW THAT EVIDENCE OUT AND WE'LL ARGUE IT AS
09:15AM 18 APPROPRIATE IN THE CASE.

09:15AM 19 BUT I THINK -- I UNDERSTAND THE CONCERN AND I UNDERSTAND
09:15AM 20 THAT THERE MAY BE SOME DESIRE TO AVOID THAT. THE SPECIFIC
09:15AM 21 ISSUE THAT THE COURT HAS RAISED SHOULD NOT BE A CONCERN.

09:15AM 22 THE COURT: GREAT. OKAY.

09:15AM 23 MR. SCHENK, ANYTHING ELSE?

09:15AM 24 MR. SCHENK: NOTHING FURTHER.

09:15AM 25 THE COURT: GREAT. I THINK IT'S IMPORTANT THAT WE

09:15AM 1 HAVE THESE DISCUSSIONS NOW AT THIS HEARING AS BOTH SIDES
09:15AM 2 CONTINUE TO PREPARE YOUR CASES, AND THIS IS INFORMATIVE FOR THE
09:15AM 3 COURT ALSO TO RECOGNIZE IN MY NOTES WHAT WE MIGHT ANTICIPATE
09:15AM 4 AND THOSE ISSUES THAT WOULD COME UP.

09:15AM 5 SO THIS MOTION -- I THINK IN REGARDS TO THE MOTION I'LL
09:15AM 6 DEFER THE MOTION AND RECOGNIZING THE ISSUES THAT ARE PRESENTED,
09:16AM 7 THE STATEMENTS OF BOTH COUNSEL, AND SHOULD THIS COME UP, THE
09:16AM 8 COURT WILL RULE ON ANY SPECIFIC AREA AS NEEDED DURING THE
09:16AM 9 TRIAL.

09:16AM 10 ALL RIGHT. THANK YOU.

09:16AM 11 NEXT I BELIEVE IS GOVERNMENT'S MOTION IN LIMINE NUMBER 5,
09:16AM 12 TO PRECLUDE THE DEFENDANT FROM PRESENTING AN IMPROPER
09:16AM 13 GOOD-FAITH DEFENSE.

09:16AM 14 MR. BOSTIC.

09:16AM 15 MR. BOSTIC: YES, YOUR HONOR. GOOD MORNING.

09:16AM 16 JOHN BOSTIC FOR THE UNITED STATES.

09:16AM 17 I BELIEVE THERE'S A SIGNIFICANT AMOUNT OF AGREEMENT ON
09:16AM 18 THIS MOTION ALSO BETWEEN THE PARTIES. THERE SEEMS TO BE NO
09:16AM 19 DISPUTE THAT THE NINTH CIRCUIT HAS CLEARLY LAID OUT THE LAW,
09:16AM 20 THE RULE THAT A GOOD FAITH BELIEF THAT A FRAUD VICTIM WILL BE
09:16AM 21 REPAID IS NO DEFENSE TO A CHARGE OF FRAUD.

09:16AM 22 SO IN THIS CASE, OF COURSE, BASED ON THE ELEMENTS, THE
09:16AM 23 FOCUS OF THE JURY -- THE FOCUS OF THE EVIDENCE AT TRIAL WILL BE
09:16AM 24 ON THE DEFENDANT'S STATE OF MIND AND HER INTENT AT THE TIME THE
09:17AM 25 FRAUD WAS CARRIED OUT.

09:17AM 1 OF COURSE BOTH CATEGORIES OF FRAUD IN THE INDICTMENT ARE
09:17AM 2 BASED ON THE VICTIM SCHEMES TO DEFRAUD FIRST INVESTORS, AND
09:17AM 3 ALSO PATIENTS, AND TO SEPARATE THEM FROM THEIR MONEY BY
09:17AM 4 MISLEADING STATEMENTS.

09:17AM 5 THOSE DEFENSES CRIMINALIZE THE SCHEME TO DEFRAUD ITSELF.
09:17AM 6 SO, IN FACT, THE OFFENSES, ALONG WITH THE CONSPIRACY OFFENSES,
09:17AM 7 ARE COMPLETE BEFORE THE VICTIMS ARE EVEN SEPARATED FROM THEIR
09:17AM 8 MONEY.

09:17AM 9 THE PLANS DOWN THE ROAD OF A DEFENDANT TO RESTORE PROPERTY
09:17AM 10 OR MONEY TO VICTIMS HAVE NO IMPORT IN A TRIAL OF THIS KIND.
09:17AM 11 THEY HAVE NO EFFECT ON WHETHER FRAUD HAS BEEN COMMITTED.
09:17AM 12 EFFORTS TO RESTORE MONEY TO VICTIMS CANNOT UNDO A FRAUD OFFENSE
09:17AM 13 ONCE IT'S BEEN COMMITTED.

09:17AM 14 AND CRITICALLY FROM THE BENNY OPINION IN THE
09:18AM 15 NINTH CIRCUIT, THAT'S 786 F.2D 1410, THE DEFENDANT'S INTENT
09:18AM 16 THAT VICTIMS OF THE FRAUD ULTIMATELY BE REPAID OR HAVE THEIR
09:18AM 17 PROPERTY RESTORED IS NOT A PROPER DEFENSE TO ASSERT AT TRIAL.

09:18AM 18 SO THE GOVERNMENT IS SIMPLY SEEKING AN ORDER FROM THE
09:18AM 19 COURT ENFORCING THE RULE THAT BOTH PARTIES SEEM TO RECOGNIZE.

09:18AM 20 THE DEFENSE OBJECTS THAT THEY SHOULD BE PERMITTED,
09:18AM 21 HOWEVER, TO ARGUE THAT THE DEFENDANT HAD A GOOD FAITH BELIEF IN
09:18AM 22 THE TRUTH OF ANY REPRESENTATION THAT SHE MADE.

09:18AM 23 THE GOVERNMENT IS NOT SEEKING TO PRECLUDE THOSE ASSERTIONS
09:18AM 24 OR THAT ARGUMENT. AND, IN FACT, THE GOVERNMENT ITSELF QUOTED
09:18AM 25 THE LANGUAGE IN BENNY THAT MAKES IT CLEAR THAT THAT IS A

09:18AM 1 PERMISSIBLE TYPE OF GOOD FAITH DEFENSE.

09:18AM 2 THE GOVERNMENT'S MOTION IS SIMPLY SEEKING TO PRECLUDE AN
09:18AM 3 IMPROPER GOOD FAITH DEFENSE AND BELIEVES THE COURT IS CAPABLE
09:18AM 4 OF CRAFTING AN ORDER THAT WILL ENFORCE THAT RULE.

09:18AM 5 THE COURT: THANK YOU.

09:18AM 6 MR. WADE, I THINK WHEN I LOOKED AT THIS, I THINK IT ASKED
09:19AM 7 US TO EITHER CONCUR OR NOT IN THE DECISION IN BENNY.

09:19AM 8 MR. WADE: YOUR HONOR, I DON'T THINK WE NEED AN
09:19AM 9 ORDER THAT WE HAVE TO ADHERE TO THE LAW OF THE NINTH CIRCUIT.
09:19AM 10 I THINK THE NINTH CIRCUIT IS BINDING PRECEDENT AND WE HAVE TO
09:19AM 11 ADHERE TO IT.

09:19AM 12 BENNY IS A VERY LIMITED HOLDING. A PROFFERED INSTRUCTION
09:19AM 13 THERE WAS A DEFENSE INSTRUCTION ON A GOOD FAITH INTENT TO
09:19AM 14 REPAY. THAT INSTRUCTION WAS DENIED.

09:19AM 15 IT SHOULD BE DENIED HERE IF WE OFFER IT. I SUGGEST WE
09:19AM 16 DON'T INTEND TO OFFER IT. I THINK THE BRIEFING MAKES CLEAR
09:19AM 17 THAT WE KNOW WHERE THE LINES ARE ON GOOD FAITH AND I DON'T
09:19AM 18 THINK AN ORDER IS NEEDED HERE.

09:19AM 19 I THINK THIS ONE CAN BE EITHER DENIED OR DEFERRED AS THE
09:19AM 20 EVIDENCE IS CONSIDERED THROUGHOUT THE CASE.

09:19AM 21 I WOULD LIKE TO MAKE CLEAR, WE -- COUNSEL FOR THE
09:19AM 22 GOVERNMENT SORT OF BLENDED A LITTLE BIT BETWEEN STATE OF MIND
09:20AM 23 AND ACTUS REUS IN SOME OF THE DISCUSSIONS ABOUT EFFORTS TO DO
09:20AM 24 THINGS, AND THAT'S NOT IN THIS MOTION.

09:20AM 25 THIS MOTION RELATES TO GOOD FAITH INTENT. THAT WILL

09:20AM 1 UNDOUBTEDLY BE A PART OF THIS CASE.

09:20AM 2 THE COURT: SURE. OKAY. THANK YOU.

09:20AM 3 MR. WADE: THANK YOU.

09:20AM 4 THE COURT: THANK YOU VERY MUCH. THANK YOU.

09:20AM 5 WELL, LET ME SAY IN REGARDS TO THIS MOTION, THAT IS,

09:20AM 6 GOVERNMENT'S MIL NUMBER 5, THE COURT WILL -- AS MR. WADE

09:20AM 7 SUGGESTS AND RECOGNIZES, THE COURT WILL FOLLOW THE LAW OF THE

09:20AM 8 NINTH CIRCUIT AND THAT, OF COURSE, INCLUDES A HOLDING IN THE

09:20AM 9 DIRECTION THAT THE NINTH CIRCUIT PROVIDED US, UNITED STATES

09:20AM 10 VERSUS BENNY -- EXCUSE ME -- 786 F.2D 1210, AND THE COURT

09:20AM 11 INTENDS TO FOLLOW THE PRECEDENT IN THAT CASE, AND I APPRECIATE

09:20AM 12 COUNSEL RECOGNIZING THAT AND AGREE TO FOLLOW IT AS WELL.

09:20AM 13 CONCURRENT WITH THIS IS, PURSUANT TO MR. BOSTIC'S

09:20AM 14 OBSERVATION, THIS DOES NOT PRECLUDE THE DEFENDANT OR THE

09:21AM 15 DEFENSE FROM ARGUING A GOOD FAITH BELIEF AS A DEFENSE. THAT'S

09:21AM 16 THE SECOND PART THAT WAS IDENTIFIED IN BENNY THAT IS PRECLUDED

09:21AM 17 IN THIS CASE.

09:21AM 18 SO THANK YOU FOR THAT.

09:21AM 19 NOW WE COME TO 560, WHICH IS MS. HOLMES'S MOTION REGARDING

09:21AM 20 DR. MASTER.

09:21AM 21 MS. SAHARIA: GOOD MORNING, YOUR HONOR.

09:21AM 22 THE COURT: GOOD MORNING.

09:21AM 23 MS. SAHARIA: AMY SAHARIA FOR MS. HOLMES.

09:21AM 24 THE COURT: THANK YOU. GOOD MORNING.

09:21AM 25 MAY I MAKE SOME OBSERVATIONS THAT MIGHT BE HELPFUL HERE?

09:21AM 1 I HOPE THEY'RE HELPFUL. I DON'T KNOW.

09:21AM 2 MS. SAHARIA: YES, OF COURSE, YOUR HONOR.

09:21AM 3 THE COURT: YOU CAN TELL ME IF THEY ARE OR NOT AND
09:21AM 4 I'M HAPPY TO RECEIVE THAT.

09:21AM 5 SO I READ THIS -- AND THIS IS A VERY INVOLVED AREA, OF
09:21AM 6 COURSE, WHENEVER WE'RE TALKING ABOUT THE EXPERT PIECE OF A
09:21AM 7 PROFFERED WITNESS HERE, AND HERE WE'RE SPEAKING -- THIS MOTION
09:22AM 8 SPEAKS TO DR. STEPHEN MASTER, THAT'S THE GOVERNMENT'S EXPERT
09:22AM 9 WHO HAS BEEN IDENTIFIED AS THE EXPERT HERE.

09:22AM 10 THERE ARE DIFFERENT AREAS AND TOPICS THAT THIS WITNESS
09:22AM 11 WOULD -- THAT THE GOVERNMENT SEEKS THIS WITNESS TO TESTIFY
09:22AM 12 ABOUT. THERE'S A COUPLE OF ISSUES -- LET ME JUST TELL YOU, I
09:22AM 13 THINK I'LL INDICATE IT THIS WAY: THE COURT CAN GIVE, I HOPE I
09:22AM 14 CAN GIVE YOU THIS FOR SOME BENEFIT TO YOU FOR YOUR DISCUSSION,
09:22AM 15 AND I DON'T KNOW WHO IS SPEAKING TO THIS.

09:22AM 16 MR. LEACH, ARE YOU TALKING?

09:22AM 17 MR. LEACH: I WILL BE SPEAKING TO THIS, YES.

09:22AM 18 THE COURT: OKAY. GREAT. THANK YOU.

09:22AM 19 SO IN READING YOUR PLEADINGS, AND AS THEY ALWAYS ARE IN
09:22AM 20 THIS CASE, THEY'RE VERY THOROUGH AND VERY HELPFUL, I LOOK AT
09:22AM 21 THE INDUSTRY STANDARDS AND THE QUESTION ABOUT WHETHER OR NOT
09:22AM 22 THIS WITNESS CAN TESTIFY ABOUT INDUSTRY STANDARDS.

09:22AM 23 AND I DO BELIEVE THAT THE WITNESS -- AND AGAIN, THIS IS MY
09:22AM 24 PRELIMINARY OBSERVATIONS -- THAT HE IS QUALIFIED TO TESTIFY
09:23AM 25 ABOUT INDUSTRY STANDARDS. I THINK HE DOES HAVE, AND HIS

09:23AM 1 INFORMATION THAT I'VE RECEIVED SUGGESTS, THAT HE DOES HAVE THE
09:23AM 2 BACKGROUND, THE ABILITY, THE KNOWLEDGE TO TESTIFY ABOUT THIS,
09:23AM 3 INDUSTRY STANDARDS, AS LONG AS HE DOES NOT PROVIDE LEGAL
09:23AM 4 OPINIONS. AND I WOULDN'T ALLOW HIM TO OPINE WITH ANY LEGAL
09:23AM 5 OPINIONS AS TO INDUSTRY STANDARDS.

09:23AM 6 AS TO FINGERSTICK, FINGERSTICK TECHNOLOGY, I DO THINK THAT
09:23AM 7 HE IS QUALIFIED, BASED ON HIS BACKGROUND AND HIS KNOWLEDGE, TO
09:23AM 8 OPINE ON FINGERSTICK BLOOD TESTING. HE IS A CLINICAL
09:23AM 9 PATHOLOGIST AND HE HAS GREAT EXPERIENCE IN THAT BACKGROUND IN
09:23AM 10 THOSE AREAS, AND I DO THINK HE CAN TESTIFY AS TO THIS TESTING
09:23AM 11 AND OFFER AN OPINION ABOUT THAT.

09:23AM 12 NOTWITHSTANDING THE FACT -- AND I UNDERSTAND THE DEFENSE
09:23AM 13 IS CRITICAL OF HIM BECAUSE HE DOES NOT HAVE HANDS-ON, IF YOU
09:24AM 14 WILL, EXPERIENCE IN THAT REGARD. BUT, AGAIN, I DO THINK THIS
09:24AM 15 IS A PRELIMINARY RULING.

09:24AM 16 GETTING INTO THE SPECIFIC TESTIMONY ABOUT THE DIFFERENT
09:24AM 17 ASSAYS, I DO HAVE SOME ISSUES ABOUT SOME OF THOSE. LET ME JUST
09:24AM 18 INDICATE THAT I DO THINK THAT HIS OPINIONS ON VITAMIN D AND
09:24AM 19 CHOLESTEROL ARE PERMITTED. HE WOULD BE PERMITTED TO TESTIFY ON
09:24AM 20 THOSE.

09:24AM 21 IT SEEMS FROM YOUR PLEADINGS THAT THE GOVERNMENT AND THE
09:24AM 22 DEFENSE, I THINK YOU BOTH RECOGNIZE THAT HIS OPINIONS ON
09:24AM 23 THOSE -- AS TO THOSE TWO SUBSTANCES, ASSAYS, DERIVED FROM THE
09:24AM 24 ICAHN, I-C-A-H-N, AND THE CMS REPORT, AND THOSE ARE PROPER
09:24AM 25 SOURCES FROM WHICH TO BASE AN OPINION.

09:24AM 1 I DO THINK THAT HIS OPINION ON THOSE ARE APPROPRIATELY
09:24AM 2 SUPPORTED AND HE WOULD BE PERMITTED TO TESTIFY HIS OPINIONS ON
09:24AM 3 THOSE ASSAYS.

09:25AM 4 THE POTASSIUM, CHLORIDE SODIUM, AND THE OTHERS, I THINK I
09:25AM 5 HAVE SOME PROBLEMS WITH. I THINK THERE ARE SOME DEFICIENCIES
09:25AM 6 AS TO AT LEAST WHAT WE HAVE IN HIS 20-PAGE REPORT AND I DO FIND
09:25AM 7 SOME PROBLEMS.

09:25AM 8 THIS IS TO THE GOVERNMENT I SUPPOSE I'M SPEAKING. I DO
09:25AM 9 HAVE SOME ISSUES WITH THOSE OPINIONS, AND IT WOULD BE THE
09:25AM 10 COURT'S INTENT TO SCHEDULE A DAUBERT HEARING AS TO THOSE
09:25AM 11 OPINIONS. I THINK IT WOULD BE APPROPRIATE TO ALLOW THE
09:25AM 12 GOVERNMENT AND DR. MASTER TO PROVIDE ADDITIONAL INFORMATION
09:25AM 13 THAT WOULD ENABLE THE COURT TO DETERMINE WHETHER OR NOT THOSE
09:25AM 14 OPINIONS CAN BE SUPPORTED, SUBSTANTIATED FURTHER.

09:25AM 15 AND HE MAY BE ABLE TO PROVIDE ADDITIONAL INFORMATION
09:25AM 16 BEYOND HIS 20-PAGE REPORT. I THINK 10 PAGES OF IT WERE TALKING
09:25AM 17 ABOUT BACKGROUND AND THE TESTING PROCEDURES, AND THEN THERE
09:26AM 18 WERE -- THE BALANCE I THINK DRILLED DOWN INTO THESE ISSUES.

09:26AM 19 I'M NOT BEING CRITICAL OF THE REPORT. WHAT I'M SAYING IS
09:26AM 20 THAT I THINK I NEED MORE BEFORE I WOULD PERMIT HIM TO TESTIFY.

09:26AM 21 AND I'M GOING TO GIVE THE GOVERNMENT THAT OPPORTUNITY,
09:26AM 22 THROUGH A DAUBERT HEARING, FOR THOSE PARTICULAR TOPICS.

09:26AM 23 MS. SAHARIA: THANK YOU, YOUR HONOR. I THINK THAT'S
09:26AM 24 HELPFUL AND THAT WILL HELP STREAMLINE MY PRESENTATION
09:26AM 25 SIGNIFICANTLY.

09:26AM 1 SO I THINK MAYBE I CAN TAKE THIS IN MAYBE THREE BUCKETS.

09:26AM 2 LET ME START WITH THE ASSAYS, AND LET ME START WITH THE
09:26AM 3 EIGHT THAT YOUR HONOR INDICATED THAT YOU HAVE CONCERNS WITH,
09:26AM 4 WHICH WE, OF COURSE, SHARE.

09:26AM 5 THEN I'LL MOVE AND DISCUSS CHOLESTEROL AND VITAMIN D, AND
09:26AM 6 THEN I'LL CONCLUDE WITH INDUSTRY STANDARDS.

09:26AM 7 I DO THINK THAT IT WOULD BE IMPERMISSIBLE FOR THE COURT TO
09:27AM 8 ALLOW DR. MASTER TO OPINE AS TO THOSE EIGHT ASSAYS WITHOUT
09:27AM 9 AFFORDING THE DEFENSE A DAUBERT HEARING. LET ME TRY TO
09:27AM 10 CONVINCE THE COURT WHY WE DON'T EVEN THINK THAT YOU SHOULD GET
09:27AM 11 TO A DAUBERT HEARING, BECAUSE HIS OPINIONS ON THOSE EIGHT
09:27AM 12 ASSAYS ARE SO DEFICIENT.

09:27AM 13 AND I THINK IT'S TELLING THAT YOUR HONOR POINTED OUT THAT
09:27AM 14 KIND OF A PAUCITY OF INFORMATION IN HIS REPORT ON THOSE ASSAYS.

09:27AM 15 I THINK WHAT IS ALSO TELLING IS THE PAUCITY OF THE
09:27AM 16 GOVERNMENT'S DEFENSE OF THOSE OF ASSAYS. THEIR OPPOSITION
09:27AM 17 BRIEF IS ECF 668, AND THEY DEFEND HIS OPINIONS AS TO THE ASSAYS
09:27AM 18 ON PAGES 6 TO 9 OF THAT BRIEF. AND THEY CITE NO CASE, THERE'S
09:27AM 19 NO CASE IN THEIR OPPOSITION DEFENDING DR. MASTER'S OPINIONS ON
09:27AM 20 THOSE ASSAYS.

09:27AM 21 THEY CITE KIND OF THE GENERIC DAUBERT PRINCIPLES IN THE
09:27AM 22 BEGINNING OF THEIR BRIEF, BUT WHEN IT COMES TO SHOWING THE
09:27AM 23 COURT ANOTHER CASE WHERE A COURT HAS ALLOWED AN EXPERT TO OFFER
09:28AM 24 SCIENTIFIC OPINIONS BASED ON EMAILS AND CUSTOMER COMPLAINTS.
09:28AM 25 THEY HAVE NO CASE, NO CASE THAT HAS SUBMITTED SIMILAR OPINIONS.

09:28AM 1 THEY CITE NO SCIENTIFIC LITERATURE THAT ESTABLISHES THAT
09:28AM 2 IS A SCIENTIFICALLY VALID WAY TO REACH THESE SCIENTIFIC
09:28AM 3 CONCLUSIONS, AND THAT'S BECAUSE IT IS NOT A SCIENTIFICALLY
09:28AM 4 VALID WAY TO REACH OPINIONS ON THE SCIENTIFICALLY COMPLEX ISSUE
09:28AM 5 OF ACCURACY AND RELIABILITY.

09:28AM 6 THAT SHOULD GIVE THE COURT GREAT PAUSE, AND WE WOULD
09:28AM 7 WELCOME A DAUBERT HEARING IF THAT'S WHAT THE COURT DECIDES TO
09:28AM 8 DO, BUT NO HEARING IS GOING TO SUPPLANT THAT -- IS GOING TO
09:28AM 9 PRODUCE MATERIAL THAT DOESN'T EXIST. THE DATA DOESN'T EXIST.
09:28AM 10 WE KNOW WHY IT DOESN'T EXIST. WE TALKED ABOUT THAT YESTERDAY,
09:28AM 11 AND THAT'S WHY DR. MASTER IS LEFT TO OFFER OPINIONS BASED ON
09:28AM 12 EMAILS AND CUSTOMER COMPLAINTS.

09:28AM 13 THE EIGHT ASSAYS THAT YOUR HONOR INDICATED, THEY FALL INTO
09:29AM 14 TWO BUCKETS. AS I THINK YOU KNOW, FOUR OF THOSE, WHICH ARE --
09:29AM 15 CAN I JUST PUT UP THE ELMO?

09:29AM 16 MR. WADE: YES.

09:29AM 17 MS. SAHARIA: THANK YOU.

09:29AM 18 YOUR HONOR, THIS IS APPENDIX A TO OUR MOTION, AND THOSE
09:29AM 19 EIGHT ASSAYS FALL INTO TWO GROUPS. THERE ARE FOUR WHICH ARE
09:29AM 20 CALCIUM, HBA1C, HCG, AND HIV, THESE ARE THE ASSAYS FOR WHICH
09:29AM 21 DR. MASTER WAS ASKED TO OFFER AN OPINION THAT THE ASSAYS ARE
09:29AM 22 ACCURATE AND RELIABLE, AND HE WAS UNABLE TO REACH THAT OPINION.

09:29AM 23 AT EXHIBIT 9 OF OUR EXHIBITS, HE EXPLAINED THAT TO FULLY
09:29AM 24 RENDER THE OPINION THAT THE GOVERNMENT WAS LOOKING FOR, HE WAS
09:29AM 25 LOOKING FOR DOCUMENTS THAT SPECIFICALLY RELATE TO THESE FOUR

09:30AM 1 ASSAYS, AND PRESUMABLY THE GOVERNMENT WAS UNABLE TO GIVE HIM
09:30AM 2 THOSE DOCUMENTS BECAUSE HE WAS UNABLE TO OFFER AN ACTUAL
09:30AM 3 OPINION ABOUT ACCURACY AND RELIABILITY.

09:30AM 4 HE ESSENTIALLY, AS TO THESE FOUR, OFFERS A NONOPINION. HE
09:30AM 5 SAID, AND I QUOTE AT REPORT 15, "BASED ON CUSTOMER COMPLAINTS
09:30AM 6 ON THERANOS'S INTERNAL INVESTIGATIONS, THERE WERE SIGNIFICANT
09:30AM 7 ISSUES WITH CALCIUM, HBA1C, HCG, AND HIV DURING THE TIMES THAT
09:30AM 8 THESE WERE PERFORMED ON FINGERSTICK SAMPLES. IN SOME CASES
09:30AM 9 THERE ARE INSUFFICIENT ADDITIONAL DETAILS OF THE MATERIAL I
09:30AM 10 HAVE REVIEWED TO DETERMINE THE CAUSE OF THESE ISSUES, THE
09:30AM 11 RELATIONSHIP TO ADDED EITHER THE SAMPLE TYPE OR THERANOS'S
09:30AM 12 TECHNOLOGY OR THE RESOLUTION OF THE PROBLEM."

09:30AM 13 WE DON'T KNOW WHAT HE MEANS BY "ISSUES," WE DON'T KNOW
09:30AM 14 WHAT CUSTOMER COMPLAINTS HE LOOKED AT, AND HE DOES NOT
09:30AM 15 ARTICULATE THAT THAT IS A VALID SCIENTIFIC METHODOLOGY TO REACH
09:30AM 16 AN OPINION, AND HE DOESN'T EVEN REACH AN OPINION. HE DOESN'T
09:30AM 17 HAVE AN OPINION AS TO THESE FOUR. THEY MIGHT BE INACCURATE,
09:31AM 18 THEY MIGHT NOT BE INACCURATE, AND THAT'S COMPLETELY UNHELPFUL
09:31AM 19 TO A JURY.

09:31AM 20 I THINK IN THAT REGARD HIS OPINION AS TO THESE FOUR ARE
09:31AM 21 JUST LIKE THE OPINIONS THAT THE NINTH CIRCUIT REJECTED IN
09:31AM 22 DAUBERT ON REMAND FROM THE SUPREME COURT WHERE THE EXPERT
09:31AM 23 ADVANCED THE OPINION THAT A MEDICATION COULD POSSIBLY HAVE
09:31AM 24 CAUSED INJURIES, AND THE NINTH CIRCUIT SAID THAT KIND OF
09:31AM 25 POSSIBLE CAUSE OPINION IS NOT HELPFUL TO A JURY AND IS

09:31AM 1 INADMISSIBLE.

09:31AM 2 AND THAT'S EFFECTIVELY WHAT DR. MASTER IS OFFERING AS TO
09:31AM 3 THESE FOUR. THERE MIGHT BE PROBLEMS. I DON'T KNOW WHAT THE
09:31AM 4 PROBLEMS ARE, I DON'T KNOW WHAT CAUSED THEM. JURY, YOU FIGURE
09:31AM 5 THAT OUT.

09:31AM 6 THAT'S NOT A PROPER EXPERT OPINION.

09:31AM 7 AS TO THE REMAINING FOUR IN THIS FIRST BUCKET -- AND THOSE
09:31AM 8 ARE, JUST FOR THE RECORD, BICARBONATE, CHLORIDE, POTASSIUM, AND
09:32AM 9 SODIUM -- I THINK THE COURT CAN AT THIS STAGE EASILY EXCLUDE
09:32AM 10 HIS OPINION ON BICARBONATE. HE OFFERS NO BASIS WHATSOEVER, AND
09:32AM 11 THE GOVERNMENT DIDN'T DEFEND THAT ONE IN ITS OPPOSITION.

09:32AM 12 AS TO CHLORIDE, SODIUM, AND POTASSIUM, AGAIN, DR. MASTER
09:32AM 13 BASES HIS OPINION ON UNIDENTIFIED CUSTOMER COMPLAINTS AND
09:32AM 14 INTERNAL EMAILS.

09:32AM 15 AND WHEN WE INDICATED IN OUR MOTION THAT THAT IS NOT A
09:32AM 16 PROPER METHODOLOGY, THE MOST THE GOVERNMENT COULD MUSTER IS
09:32AM 17 THAT THAT METHODOLOGY IS IMPLICIT IN HIS OPINION.

09:32AM 18 THAT CLEARLY IS A RED FLAG BECAUSE THE NINTH CIRCUIT
09:32AM 19 REQUIRES THAT AN EXPERT EXPRESSLY STATE HIS METHODOLOGY.

09:32AM 20 AGAIN, THE GOVERNMENT HAS CITED THE COURT TO ZERO CASES,
09:32AM 21 ZERO ACADEMIC LITERATURE ESTABLISHING THAT TO BE A VALID
09:32AM 22 METHODOLOGY FOR A SCIENTIST TO REACH SCIENTIFIC CONCLUSIONS.

09:33AM 23 SO UNLESS THE COURT HAS QUESTIONS ABOUT THOSE EIGHT, LET
09:33AM 24 ME MOVE TO CHOLESTEROL AND VITAMIN D.

09:33AM 25 THE COURT: THAT'S FINE, THANK YOU.

09:33AM 1 MS. SAHARIA: AS TO THE CHOLESTEROL OPINION, AS
09:33AM 2 YOUR HONOR INDICATED, DR. MASTER IS PRIMARILY BASING HIS
09:33AM 3 OPINION ON THE ICAHN STUDY. THIS IS A STUDY OF 60 PATIENTS IN
09:33AM 4 WHICH THE STUDY AUTHORS ORDERED THE SAME TESTS FROM THOSE
09:33AM 5 PATIENTS FROM BOTH THERANOS AND FROM TWO OTHER LAB COMPANIES.

09:33AM 6 I THINK JUST TO EXPLAIN THE RESULTS OF THAT STUDY, IN
09:33AM 7 FACT, THE STUDY AUTHORS CONCLUDED THAT FOR VIRTUALLY ALL OF THE
09:33AM 8 TESTS, THE THERANOS RESULTS AGREED WITH THE RESULTS FROM THOSE
09:33AM 9 OTHER LABS WITH THE EXCEPTION OF WITH THE EXCEPTION OF THE
09:33AM 10 LIPID PANEL, AND THE LIPID PANEL IS A PANEL THAT INCLUDES
09:33AM 11 CHOLESTEROL ASSAYS.

09:33AM 12 TELLINGLY, NO ONE INVOLVED IN THAT STUDY OF THE IS ON THE
09:33AM 13 GOVERNMENT'S LIST, AND THAT'S BECAUSE THE STUDY AUTHORS DID NOT
09:33AM 14 REACH THE CONCLUSION THAT DR. MASTER REACHES.

09:33AM 15 THE STUDY AUTHORS DID NOT REACH OPINIONS ON ACCURACY AND
09:34AM 16 RELIABILITY. THE STUDY WAS NOT AIMED AT MEASURING THAT.

09:34AM 17 INSTEAD IT WAS AIMED AT MEASURING WHETHER THERANOS RESULTS
09:34AM 18 WERE CONSISTENT WITH THE RESULTS FROM OTHER -- FROM THESE OTHER
09:34AM 19 COMPANIES.

09:34AM 20 NOW, DR. MASTER HIMSELF ACKNOWLEDGES IN HIS REPORT THAT
09:34AM 21 THERE ARE HARMONIZATION AND STANDARDIZATION ISSUES BETWEEN
09:34AM 22 COMPANIES AND THAT'S NORMAL AND EXPECTED AT PAGE 14 OF HIS
09:34AM 23 REPORT.

09:34AM 24 HE STATED AS A GENERAL PRINCIPLE THAT FOR MANY ANALYSTS,
09:34AM 25 THERE ARE ISSUES OF STANDARDIZATION AND HARMONIZATION BETWEEN

09:34AM 1 ASSAYS USED BY VARIOUS CLINICAL LABORATORIES.

09:34AM 2 AND THE PROBLEM WITH HIS CONCLUSION HERE IS THAT HE DIDN'T
09:34AM 3 ARTICULATE ANY METHODOLOGY BY WHICH HE CONCLUDED THAT THE
09:34AM 4 DIFFERENCES AS TO THE CHOLESTEROL ASSAY IN THIS CASE WERE
09:34AM 5 SIMPLY ISSUES OF STANDARDIZATION AND HARMONIZATION THAT WAS
09:34AM 6 EXPECTED, OR WHETHER THEY RESULTED FROM SOME MORE FUNDAMENTAL
09:35AM 7 PROBLEM WITH THE THERANOS CHOLESTEROL TEST. HE DID NOT
09:35AM 8 ARTICULATE HOW HE REACHED THAT CONCLUSION.

09:35AM 9 NOW, AS YOUR HONOR INDICATED, IT IS APPROPRIATE FOR
09:35AM 10 EXPERTS TO BASE OPINIONS ON ACADEMIC ARTICLES, AND THAT'S THE
09:35AM 11 GOVERNMENT'S PRIMARY RESPONSE. BUT THERE ARE MANY CASES,
09:35AM 12 INCLUDING THE SUPREME COURT DECISION IN GENERAL ELECTRIC VERSUS
09:35AM 13 JOINER, THAT SAY THAT EXPERTS CANNOT RELIABLY BASE AN OPINION
09:35AM 14 ON AN ACADEMIC ARTICLE WHEN THEY GO BEYOND THE CONCLUSIONS OF
09:35AM 15 THAT ACADEMIC ARTICLE ITSELF UNLESS THEY ARTICULATE SOME
09:35AM 16 METHODOLOGY BY WHICH THEY WERE ABLE TO EXTRACT A BROADER
09:35AM 17 OPINION THAN THE ARTICLE DID.

09:35AM 18 THAT'S EXACTLY WHAT WE HAVE HERE WITH DR. MASTER.

09:35AM 19 SO I WOULD SUBMIT THAT AT A MINIMUM, THE COURT SHOULD NOT
09:35AM 20 ADMIT THE OPINION AS TO CHOLESTEROL UNTIL WE HAVE A CHANCE TO
09:35AM 21 EXAMINE DR. MASTER AT A DAUBERT HEARING TO SEE WHETHER HE WAS
09:35AM 22 ABLE TO REACH AN OPINION THAT THE STUDY AUTHORS THEMSELVES DID
09:35AM 23 NOT REACH, ESPECIALLY WHEN HE HIMSELF RECOGNIZES THAT THERE ARE
09:36AM 24 THESE HARMONIZATION ISSUES ACROSS LABORATORIES.

09:36AM 25 WITH RESPECT TO VITAMIN D, DR. MASTER BASES HIS OPINION ON

09:36AM 1 THE CMS REPORT AND MY COLLEAGUE, MR. LOOBY IS GOING TO DISCUSS
09:36AM 2 THE CMS REPORT IN MORE DETAIL WITH THE CMS MOTION.

09:36AM 3 AS HE WILL EXPLAIN, CMS DID NOT ITSELF MEASURE ACCURACY
09:36AM 4 AND LIABILITY IN ASSAYS. THERE'S NO FINDING BY CMS THAT
09:36AM 5 THERANOS, ITS VITAMIN D WAS INACCURATE OR UNRELIABLE.

09:36AM 6 AND DR. MASTER IN HIS REPORT SIMPLY PLUCKS OUT SOME DATA
09:36AM 7 IN THE CMS REPORT THAT RELATES TO ONLY THREE DEVICES, ONE FOR A
09:36AM 8 ONE WEEK PERIOD AND TWO FOR A ONE MONTH PERIOD.

09:36AM 9 AND HE DOESN'T EXPLAIN HOW HE WAS ABLE TO EXTRAPOLATE FROM
09:36AM 10 THAT VERY LIMITED SET OF DATA TO A GENERAL OPINION ABOUT THE
09:36AM 11 ACCURACY AND RELIABILITY OF THE VITAMIN D ASSAY OVER A THREE
09:37AM 12 YEAR PERIOD.

09:37AM 13 SO AGAIN, I WOULD SUBMIT THAT WE SHOULD BE ENTITLED TO
09:37AM 14 EXAMINE HIM IF THERE'S GOING TO BE A DAUBERT HEARING ABOUT HOW
09:37AM 15 HE WAS ABLE TO EXTRAPOLATE IN A SCIENTIFICALLY VALID MANNER
09:37AM 16 BECAUSE HE DOESN'T EXPLAIN THAT IN HIS REPORT.

09:37AM 17 UNLESS THE COURT HAS QUESTIONS ABOUT THOSE TWO, I'LL MOVE
09:37AM 18 TO INDUSTRY STANDARDS.

09:37AM 19 THE COURT: PLEASE.

09:37AM 20 MS. SAHARIA: OKAY. SO I THINK THERE'S TWO PROBLEMS
09:37AM 21 WITH DR. MASTER'S OPINIONS ON INDUSTRY STANDARDS, AND I DON'T
09:37AM 22 QUIBBLE WITH HIS QUALIFICATIONS AS A GENERAL MATTER. HE'S
09:37AM 23 OBVIOUSLY A QUALIFIED LABORATORY DIRECTOR.

09:37AM 24 THE FIRST IS THAT HIS OPINIONS DON'T FIT THE CASE, AND
09:37AM 25 THAT'S BECAUSE HE IS UNABLE TO OFFER AN OPINION THAT ANY

09:37AM 1 SUPPOSED VIOLATIONS OF INDUSTRY STANDARDS ACTUALLY CAUSED
09:37AM 2 ACCURACY OR LIABILITY PROBLEMS AT THERANOS.

09:37AM 3 HE, AGAIN, OFFERS ONLY THE OPINION THAT THEY POSSIBLY
09:37AM 4 CAUSED THOSE PROBLEMS.

09:37AM 5 AND THIS GETS TO THE ISSUE THAT WE WERE TALKING ABOUT
09:38AM 6 YESTERDAY SOMEWHAT WITH MY COLLEAGUE, MR. FLEURMONT, WHICH IS
09:38AM 7 THIS CASE IS NOT ABOUT WHETHER THERANOS VIOLATED CLIA. IT'S
09:38AM 8 NOT ABOUT WHETHER THERANOS'S LAB OPERATED IN COMPLIANCE WITH
09:38AM 9 INDUSTRY STANDARDS.

09:38AM 10 IT'S ABOUT WHETHER MS. HOLMES MADE MISREPRESENTATIONS
09:38AM 11 RELATED TO THE ACCURACY AND RELIABILITY OF THERANOS'S TESTS.

09:38AM 12 AND IF HE'S NOT ABLE TO CONNECT THESE OPINIONS ABOUT
09:38AM 13 SUPPOSED VIOLATIONS OF INDUSTRY STANDARDS TO THE ACTUAL LEGAL
09:38AM 14 QUESTION IN THIS CASE, AND HE CONCEDES THAT THE COURT WAS
09:38AM 15 DISCUSSING WITH MR. FLEURMONT THAT HE CAN'T, THEN THERE'S --
09:38AM 16 THEN THAT LOGICAL CONNECTION THAT DAUBERT REQUIRES, THAT FIT,
09:38AM 17 IS SIMPLY MISSING FROM HIS OPINIONS.

09:38AM 18 AGAIN, THE OPINION IN THIS REGARD IS VERY MUCH LIKE THE
09:38AM 19 ONE THAT I MENTIONED IN THE DAUBERT OPINION ITSELF WHERE THE
09:38AM 20 OPINION WAS JUST THAT A CERTAIN DRUG COULD HAVE CAUSED
09:38AM 21 MEDICAL -- CERTAIN INJURIES.

09:38AM 22 HERE HE'S OPINING JUST THAT SUPPOSED VIOLATIONS OF
09:39AM 23 INDUSTRY STANDARDS COULD HAVE CAUSE ACCURACY PROBLEMS, BUT HE'S
09:39AM 24 NOT ABLE TO OPINE THAT IT ACTUALLY DID.

09:39AM 25 SO FOR THAT REASON WE THINK THIS DOES NOT FIT THE CASE.

09:39AM 1 NOW, ON THE ISSUE OF WHETHER HE IS OFFERING LEGAL
09:39AM 2 OPINIONS, I THINK IT IS CLEAR THAT HE DOES INTEND TO OFFER SOME
09:39AM 3 LEGAL OPINIONS, AND I'LL POINT THE COURT TO THE TWO MOST
09:39AM 4 OBVIOUS ONES.

09:39AM 5 AT PAGE 18 OF HIS REPORT, HE OPINES THAT THERANOS DID NOT
09:39AM 6 APPROPRIATELY ENGAGE IN PROFICIENCY TESTING. PROFICIENCY
09:39AM 7 TESTING IS GOVERNED BY CLIA AND IT'S A PROCESS BY WHICH A
09:39AM 8 LABORATORY WILL TYPICALLY OBTAIN SAMPLES FROM A THIRD PARTY AND
09:39AM 9 TEST THOSE SAMPLES TO SEE IF THEY GET THE CORRECT RESULTS.

09:39AM 10 HE ACKNOWLEDGES THAT THIS TESTING IS GOVERNED BY CLIA AT
09:39AM 11 PAGE 10, AND HE ACKNOWLEDGES THAT THERE'S SOME CIRCUMSTANCES IN
09:39AM 12 WHICH, UNDER CLIA, A LABORATORY MAY ENGAGE IN WHAT'S CALLED
09:40AM 13 ALTERNATIVE METHODS OF PROFICIENCY TESTING.

09:40AM 14 AND HE CONCLUDES THAT -- HE ACKNOWLEDGES THAT THERANOS DID
09:40AM 15 THAT, THAT IT ENGAGED IN THIS ALTERNATIVE TESTING -- AGAIN,
09:40AM 16 WHICH IS PERMITTED UNDER SOME CIRCUMSTANCES UNDER CLIA -- AND
09:40AM 17 HE ACKNOWLEDGES THAT THERANOS DID THAT BASED ON ITS
09:40AM 18 INTERPRETATION OF CLIA, BUT HE DISAGREES WITH THAT
09:40AM 19 INTERPRETATION OF CLIA -- AGAIN, THIS IS ALL AT PAGE 18 -- IN
09:40AM 20 PART BASED ON HIS OPINIONS ON WHAT THE BURDENS OF PROOF ARE
09:40AM 21 UNDER CLIA.

09:40AM 22 THAT'S CLEARLY A LEGAL OPINION.

09:40AM 23 THE COURT: SO IF HE'S PERMITTED TO TESTIFY, BUT HIS
09:40AM 24 TESTIMONY IS PARSED OUT, HE'S NOT PERMITTED TO OFFER HIS LEGAL
09:40AM 25 OPINION ABOUT WHY HE PARTS COMPANY WITH WHAT THERANOS DID OR

09:40AM 1 SOMETHING LIKE THAT, WOULD YOU STILL HAVE OBJECTIONS ABOUT HIS
09:40AM 2 TESTIMONY?

09:40AM 3 IN OTHER WORDS, CAN WE EXCISE, CAN WE SANITIZE THOSE
09:40AM 4 OPINIONS SUCH THAT THE BALANCE AND REMAINING OPINIONS WOULD BE
09:40AM 5 APPROPRIATE AND PROPER?

09:41AM 6 MS. SAHARIA: SO OUR POSITION IS THAT HE SHOULD NOT
09:41AM 7 BE PERMITTED TO EVEN OFFER THE LEGAL OPINION AS TO WHAT CLIA
09:41AM 8 REQUIRES.

09:41AM 9 BUT EVEN MORE PROBLEMATIC WOULD BE HIS APPLICATION OF THAT
09:41AM 10 LAW TO THE FACTS HERE, AND IN PARTICULAR IN THE WAY HE DOES
09:41AM 11 THAT, WHICH IS TO ACKNOWLEDGE THAT THERANOS HAD ONE
09:41AM 12 INTERPRETATION AND TO SAY THAT HE DISAGREES WITH THAT
09:41AM 13 INTERPRETATION.

09:41AM 14 SO I WOULD SAY, NO, HE SHOULD NOT BE ABLE TO TALK ABOUT
09:41AM 15 CLIA AND FEDERAL LAW AT ALL. THAT IS A LEGAL OPINION.

09:41AM 16 BUT THE MOST EGREGIOUS EXAMPLE OF THAT IS HIS DISCUSSION
09:41AM 17 OF HIS DISAGREEMENT WITH THE INTERPRETATION OF THERANOS.

09:41AM 18 THE COURT: BECAUSE HE'S, HE'S -- HE HAS EXTENSIVE
09:41AM 19 BACKGROUND. HE KNOWS ABOUT REGULATIONS. MAYBE WE'RE IN THE
09:41AM 20 MARGINS HERE ABOUT IS A REGULATION A LEGAL OPINION OR IS IT
09:41AM 21 INTERPRETATION OF GUIDANCE FROM A FEDERAL AGENCY, AND DO THOSE
09:41AM 22 INTERSECT SOMEHOW SUCH THAT THEY CHANGE CHARACTERS?

09:42AM 23 MS. SAHARIA: I DON'T THINK SO, YOUR HONOR.

09:42AM 24 A REGULATION IS BINDING LAW JUST IN THE WAY THAT A LAW IS.
09:42AM 25 IT WOULD BE ONE THING, I SUPPOSE, TO BE DISCUSSING NONBINDING

09:42AM 1 GUIDANCE THAT INFORMS HOW THE INDUSTRY OPERATES. THAT MIGHT BE
09:42AM 2 DIFFERENT.

09:42AM 3 BUT A REGULATION IS A LEGALLY BINDING OBLIGATION IN THE
09:42AM 4 SAME WAY THAT A LAW IS.

09:42AM 5 SO I DON'T VIEW THERE BEING ANY DISTINCTION BETWEEN HIM
09:42AM 6 OPINING WHAT CLIA THE FEDERAL STATUTE REQUIRE AND WHAT THE
09:42AM 7 REGULATIONS ENFORCING CLIA REQUIRE. I THINK THEY'RE THE SAME
09:42AM 8 THINGS.

09:42AM 9 I THINK WHAT IS IMPORTANT HERE -- AND I THINK IF ALL OF
09:42AM 10 THIS COMES OUT AT TRIAL RELATING TO CMS AND FDA, WHICH WE'RE
09:42AM 11 GOING TO DISCUSS THAT LATER TODAY -- BUT YOUR HONOR WILL HEAR
09:42AM 12 THAT THESE WERE TOPICS OF GREAT DEBATE AT THE TIME.

09:42AM 13 THERANOS HAD LEGAL COUNSEL ADVISING IT ON THESE VARIOUS
09:42AM 14 ISSUES, THEY WERE ENGAGED IN DISCUSSIONS WITH THE FEDERAL
09:42AM 15 AGENCIES ABOUT THESE TOPICS, AND TO ALLOW SOMEONE TO COME IN
09:43AM 16 AFTER THE FACT AND SAY, THE POSITION THAT YOU WERE TAKING WAS
09:43AM 17 INCORRECT IS I THINK HIGHLY PROBLEMATIC.

09:43AM 18 IT'S NOT ALLOWED UNDER DAUBERT, AND IT DOESN'T FALL INTO
09:43AM 19 THE BUCKET THAT WE WERE TALKING ABOUT YESTERDAY WHERE THERE WAS
09:43AM 20 SOMEONE IN REALTIME LIKE DR. ROSENDORFF, WHO THE GOVERNMENT
09:43AM 21 CLAIMS TOLD MS. HOLMES THAT HE BELIEVED THE COMPANY WAS NOT
09:43AM 22 COMPLYING WITH VARIOUS REGULATIONS AND THAT MIGHT GO TO HER
09:43AM 23 INTENT UNDER THE GOVERNMENT'S THEORY.

09:43AM 24 THIS DOESN'T FALL UNDER THAT CATEGORY OF ADMISSIBLE
09:43AM 25 EVIDENCE.

09:43AM 1 THE COURT: THIS IS DIFFERENT.

09:43AM 2 MS. SAHARIA: THIS IS VERY DIFFERENT.

09:43AM 3 SO I THINK THE SECOND REALLY GOOD EXAMPLE OF THAT -- THIS
09:43AM 4 IS AT PAGE 18 AND 19 -- WHERE HE DESCRIBES A LEGAL DISPUTE
09:43AM 5 BETWEEN THERANOS AND THE FDA REGARDING WHETHER THERANOS'S
09:43AM 6 COLLECTION DEVICE QUALIFIED AS A LABORATORY DEVELOPED TEST.

09:43AM 7 AND HE ACKNOWLEDGES AGAIN THAT THERANOS WAS ADVANCING ONE
09:43AM 8 LEGAL POSITION, AND THEN HE ARTICULATES THAT HE DISAGREES WITH
09:43AM 9 THAT LEGAL POSITION BECAUSE HE'S UNAWARE OF ANY LABORATORY THAT
09:44AM 10 HAS SIMILARLY ATTEMPTED TO ADVANCE THAT LEGAL POSITION.

09:44AM 11 I THINK THAT'S THE SAME KIND OF EXAMPLE WHERE IT WOULD BE
09:44AM 12 VERY IMPROPER TO ALLOW SOMEONE WHO IS NOT A LAWYER, EVEN THOUGH
09:44AM 13 HE IS QUALIFIED AS A LAB DIRECTOR, TO COME IN AFTER THE FACT
09:44AM 14 AND BASICALLY PUT HIS THUMB ON THE SCALE OF THE FDA'S POSITION
09:44AM 15 IN THIS LEGAL DISPUTE BETWEEN FDA AND THERANOS.

09:44AM 16 SO THOSE ARE THE VERY TWO CLEAR EXAMPLES WHERE I THINK
09:44AM 17 HE'S VERY CLEARLY ARTICULATING LEGAL OPINION.

09:44AM 18 THE COURT: OKAY. THANK YOU VERY MUCH.

09:44AM 19 MS. SAHARIA: THANK YOU.

09:44AM 20 THE COURT: MR. LEACH.

09:44AM 21 MR. LEACH: THANK YOU, YOUR HONOR. GOOD MORNING.

09:44AM 22 ROBERT LEACH ON BEHALF OF THE UNITED STATES.

09:44AM 23 THE COURT: THANK YOU. GOOD MORNING.

09:44AM 24 MR. LEACH: LET ME START OFF WITH WHERE WE ENDED THE
09:44AM 25 CONVERSATION ABOUT WHETHER DR. MASTER'S OFFERING A LEGAL

09:44AM 1 OPINION. HE IS NOT.

09:45AM 2 I THINK A HELPFUL WAY TO THINK ABOUT THIS, YOUR HONOR, IS
09:45AM 3 IN A HIGHLY REGULATED INDUSTRY LIKE THIS, THERE ARE INDUSTRY
09:45AM 4 STANDARDS THAT COMPANIES ABIDE BY TO MAKE SURE THAT THEIR TESTS
09:45AM 5 ARE ACCURATE AND RELIABLE, BECAUSE THEY WANT THEM TO BE
09:45AM 6 ACCURATE AND RELIABLE. PUTTING ASIDE ANY LAW, PUTTING ASIDE
09:45AM 7 ANY REGULATION, THERE ARE GENERALLY ACCEPTED LAB PRACTICES THAT
09:45AM 8 LABS FOLLOW IN ORDER TO ENSURE ACCURACY AND RELIABILITY, AND
09:45AM 9 ONE OF THEM IS PROFICIENCY TESTING.

09:45AM 10 NOW, IN A HIGHLY REGULATED AREA, THAT MAY GET CODIFIED
09:45AM 11 SOMEWHERE AS THE LAW THAT THEY MUST DO, AND WE DON'T INTEND TO
09:45AM 12 ELICIT FROM DR. MASTER THAT YOU MUST DO X.

09:45AM 13 BUT WE DO INTEND TO ELICIT THAT FIRST BUCKET, WHAT IS THE
09:45AM 14 INDUSTRY STANDARD? WHAT DO MOST LAB DIRECTORS, WHAT DO MOST
09:45AM 15 PEOPLE WHO ARE TRYING TO RUN A SAFE, ACCURATE, RELIABLE LAB DO
09:45AM 16 IN ORDER TO ENSURE THIS?

09:46AM 17 AND ONE OF THOSE THINGS IS PROFICIENCY TESTING. AND
09:46AM 18 DR. MASTER ESSENTIALLY CORROBORATES AND VALIDATES
09:46AM 19 DR. ROSENDORFF THAT THERANOS WAS DOING PROFICIENCY TESTING IN A
09:46AM 20 WAY THAT DID NOT ENSURE ACCURACY AND RELIABILITY.

09:46AM 21 THEY HAD THEIR EDISON DEVICE AND THEY DIDN'T DO ANY
09:46AM 22 PROFICIENCY TESTING ON THAT EDISON DEVICE.

09:46AM 23 THE PROFICIENCY TESTING THEY DID, ORDINARY FDA APPROVED
09:46AM 24 DEVICES AND ORDINARY FDA APPROVED TESTS, AND INTERNALLY THEY
09:46AM 25 COMPARED THOSE, AND THEY'RE SAYING THAT'S ENOUGH TO ENSURE

09:46AM 1 ACCURACY AND RELIABLE RESULTS.

09:46AM 2 DR. ROSENDORFF DISAGREED WITH THAT. HE RAISED THAT
09:46AM 3 REPEATEDLY.

09:46AM 4 AND DR. MASTER'S OPINION IS ESSENTIALLY THAT THE INDUSTRY
09:46AM 5 STANDARD IS CORROBORATIVE OF WHAT DR. ROSENDORFF IS SAYING.

09:46AM 6 THE COURT: I'M SORRY. SO IS THAT WHAT YOU INTEND
09:46AM 7 HIM TO SAY? IS HE GOING TO GET ON THE STAND AND SAY, I'VE READ
09:46AM 8 DR. ROSENDORFF'S REPORT, I AGREE WITH HIS FINDINGS?

09:47AM 9 MR. LEACH: I DON'T KNOW IF HE WOULD SAY THOSE EXACT
09:47AM 10 WORDS, BUT HE WOULD SAY PROFICIENCY TESTING IS DESIGNED TO
09:47AM 11 ENSURE ACCURACY AND RELIABILITY AND THE METHODS USED HERE DID
09:47AM 12 NOT DO THAT.

09:47AM 13 THE COURT: AS FOUND AND AS STATED BY
09:47AM 14 DR. ROSENDORFF?

09:47AM 15 MR. LEACH: YES, AND AS CONSISTENT WITH THE INDUSTRY
09:47AM 16 STANDARD.

09:47AM 17 THAT'S THE MOST IMPORTANT POINT. IT'S NOT JUST
09:47AM 18 DR. ROSENDORFF WHO THINKS THIS. THIS IS -- IF YOU GO INTO MOST
09:47AM 19 LABS, MOST PLACES, THIS WOULD NOT BE A WAY TO ENSURE ACCURACY
09:47AM 20 AND RELIABILITY.

09:47AM 21 SO I THINK IT'S -- A COMPANY DOES NOT GET A PASS FOR
09:47AM 22 DEVIATING FROM THE INDUSTRY STANDARD SIMPLY BECAUSE THAT
09:47AM 23 STANDARD GETS CODIFIED IN THE LAW.

09:47AM 24 AN EXPERT WHO LIVES AND BREATHESES THOSE STANDARDS AND WHO
09:47AM 25 RUNS THE LAB AND HAS THE QUALIFICATIONS THAT DR. MASTER HAS

09:47AM 1 SHOULD BE ABLE TO OFFER AN OPINION THAT I KNOW HOW TO RUN A LAB
09:47AM 2 AND I KNOW HOW TO DO IT TO MAKE TESTS ACCURATE AND RELIABLE,
09:47AM 3 AND DOING PROFICIENCY TESTING IN THIS METHOD THE WAY
09:48AM 4 DR. ROSENDORFF IS TALKING ABOUT DOESN'T FIT.

09:48AM 5 HE DOESN'T NEED TO TALK ABOUT THE CFR. HE DOESN'T NEED TO
09:48AM 6 TALK ABOUT WHAT CMS MANDATES.

09:48AM 7 BUT THE INDUSTRY STANDARD, WHAT COMPANIES ABIDE BY AS A
09:48AM 8 MATTER OF GENERALLY APPLICABLE LAB PRACTICES ARE SOMETHING THAT
09:48AM 9 HE'S EMINENTLY QUALIFIED TO TALK ABOUT AND CAN DO IN A WAY THAT
09:48AM 10 DOES NOT GIVE AN IMPERMISSIBLE LEGAL OPINION.

09:48AM 11 MS. SAHARIA DIDN'T ADDRESS THE QUALIFICATIONS TO TALK
09:48AM 12 ABOUT FINGERSTICK TECHNOLOGY, AND UNLESS THE COURT HAS
09:48AM 13 QUESTIONS, I'LL SUBMIT IT ON THE BRIEFING ON THAT POINT.

09:48AM 14 THE COURT: I THINK I'VE INDICATED MY REVIEW OF
09:48AM 15 THAT. THANK YOU.

09:48AM 16 MR. LEACH: WITH RESPECT TO THE OPINIONS ON
09:48AM 17 PARTICULAR ASSAYS, FIRST OF ALL, I DON'T THINK THE DEFENSE IS
09:48AM 18 BEING FAIR TO DR. MASTER'S OPINION ABOUT CALCIUM, HBA1C, HCG,
09:49AM 19 AND HIV.

09:49AM 20 THEY FAULT HIM FOR NOT COMING DOWN YES OR NO. HIS OPINION
09:49AM 21 IS MORE NUANCED, AND THAT'S TO HIS CREDIT, NOT TO HIS DETRIMENT
09:49AM 22 ON THAT, AND HE'S ESSENTIALLY SAYING, BASED ON THE MATERIAL
09:49AM 23 THAT I'VE REVIEWED, THERE'S SUFFICIENT PROBLEMS WITH THESE
09:49AM 24 ASSAYS WHERE IT RAISES DOUBTS IN A LAB DIRECTOR'S MIND ABOUT
09:49AM 25 WHETHER WE SHOULD OR SHOULDN'T BE USING THESE TESTS. IT'S

09:49AM 1 ESSENTIALLY, THERE ARE RED FLAGS HERE.

09:49AM 2 AND, REMEMBER, THIS IS A FRAUD CASE. MS. HOLMES WENT OUT
09:49AM 3 AND TOLD THE WORLD -- NOT THE WORLD, BUT HER INVESTORS AND
09:49AM 4 OTHERS -- THAT WE HAVE TESTS OF THE HIGHEST ACCURACY, THAT CLIA
09:49AM 5 REGULATIONS ENSURE THAT WE HAVE ACCURATE AND RELIABLE TESTS.

09:49AM 6 AND DR. MASTER'S OPINION THERE, WHICH IS BASED ON INTERNAL
09:49AM 7 THERANOS DOCUMENTS, CORROBORATED -- OR PUTS THE LIE TO THAT
09:49AM 8 ESSENTIALLY. THERE IS SUBSTANTIAL DOUBT ABOUT THESE.

09:49AM 9 AND THE FACT THAT IT'S NOT A YES OR NO IS TO HIS CREDIT,
09:50AM 10 NOT TO -- IT'S NOT A NONOPINION. IT'S AN OPINION THAT THERE
09:50AM 11 ARE ISSUES HERE ESSENTIALLY.

09:50AM 12 SO I THINK THERE'S ENOUGH THERE EVEN WITHOUT A DAUBERT
09:50AM 13 HEARING. WE INVITE THE ABILITY TO QUESTION DR. MASTER IN SUCH
09:50AM 14 A HEARING AND, TO THE EXTENT PERMITTED, SUPPLEMENT HIS VIEWS ON
09:50AM 15 THAT POINT.

09:50AM 16 WITH RESPECT TO SODIUM, CHLORIDE AND -- EXCUSE ME. LET ME
09:50AM 17 GO TO MY LIST.

09:50AM 18 WITH RESPECT TO SODIUM AND CHLORIDE, THE BASIS OF HIS
09:50AM 19 OPINIONS ARE LAID OUT PRIMARILY ON PAGE 14 AND 15 OF THE
09:50AM 20 REPORT, AND THE THRUST OF THIS IS BASED ON THE NUMBER OF
09:50AM 21 COMPLAINTS THAT THERANOS IS SEEING ON THESE PARTICULAR ASSAYS,
09:51AM 22 THESE ARE CALLED ISE ASSAYS WHICH THE THERANOS METHODS WERE
09:51AM 23 PARTICULARLY HARD TO MANAGE.

09:51AM 24 THEY'RE ALSO BASED ON TESTIMONY AND STATEMENTS BY
09:51AM 25 DR. ROSENDORFF WHERE DR. ROSENDORFF, AT THE END OF HIS TENURE,

09:51AM 1 IS SAYING, I DON'T KNOW IF WE CAN SPOT CRITICAL VALUES ONE WAY
09:51AM 2 OR THE OTHER BASED ON THE INTERNAL DOCUMENTS THAT HE WAS
09:51AM 3 LOOKING AT.

09:51AM 4 AND THE DEFENSE'S POSITION IS ESSENTIALLY A LAB DIRECTOR
09:51AM 5 IN HIS POSITION CANNOT EXERCISE PROFESSIONAL JUDGMENT ABOUT
09:51AM 6 WHAT THESE INTERNAL MEMOS AND INTERNAL ISSUES MEAN, THAT YOU
09:51AM 7 NEED TO DO SOME TYPE OF STUDY.

09:51AM 8 I'M NOT SURE HOW WE WOULD GET THESE PATIENTS FROM 2014 OR
09:51AM 9 2015 TO COME BACK IN AND TAKE THEIR BLOOD NOW AND WHETHER OR
09:51AM 10 NOT WE WOULD BE ABLE TO COMPARE THOSE.

09:51AM 11 SO I THINK THEY'RE SETTING UP A STRAW MAN THAT HE DIDN'T
09:51AM 12 DO THIS, AND THEREFORE, THERE'S NO METHOD OR REASONING TO HIS
09:51AM 13 CONCLUSIONS HERE.

09:51AM 14 BUT I DO THINK THAT THERE'S A BASIS THERE. WE'RE HAPPY TO
09:52AM 15 PRESENT MORE INFORMATION IN A DAUBERT HEARING.

09:52AM 16 AND WITH RESPECT TO VITAMIN D AND CHOLESTEROL, I THINK
09:52AM 17 THIS REALLY COMES DOWN TO WEIGHT ISSUES ABOUT HIS OPINION AND
09:52AM 18 THE APPROPRIATE INFERENCES THAT YOU CAN DRAW FROM THE CMS
09:52AM 19 REPORT AND THIS STUDY.

09:52AM 20 THE THRUST OF WHAT I ANTICIPATE FROM DR. MASTER IS THE
09:52AM 21 REFERENCE RANGES YOU SEE IN THE CMS FOR VITAMIN D, OVER THE
09:52AM 22 TIME PERIOD YOU SEE THEM, WHEN YOU COMPARE THEM TO OTHER
09:52AM 23 DEVICES THAT WERE HAVING SIMILAR ISSUES WITH DIFFERENT ASSAYS,
09:52AM 24 ARE JUST SO LONG AND SO PROFOUND THAT IT MUST BE AN INSTRUMENT
09:52AM 25 ISSUE, AND IT'S CERTAINLY AN ISSUE RUNNING THIS INSTRUMENT IN

09:52AM 1 THIS LAB.

09:52AM 2 I THINK THAT'S A FAIR CONCLUSION FROM THE CMS REPORT, AND
09:52AM 3 I THINK IT'S SOMETHING THAT A LAB DIRECTOR IS EMINENTLY
09:52AM 4 QUALIFIED TO EXTRAPOLATE FROM, AND THAT'S BOLSTERED BY THE
09:53AM 5 ICAHN STUDY, AND THERE'S A DEBATE ABOUT EXACTLY WHAT THIS MEANS
09:53AM 6 AND WHAT INFERENCES YOU CAN DRAW. I THINK THAT'S FODDER FOR
09:53AM 7 CROSS-EXAMINATION AND I DON'T THINK THAT GOES TO THE
09:53AM 8 RELIABILITY OF HIS SCIENTIFIC OPINION.

09:53AM 9 FOR THAT REASON I AGREE WITH THE COURT'S TENTATIVE THAT
09:53AM 10 THERE'S NO NEED FOR A FURTHER DAUBERT ON THAT POINT.

09:53AM 11 UNLESS THE COURT HAS FURTHER QUESTIONS, I'LL SUBMIT IT.

09:53AM 12 THE COURT: I WONDER IF YOU COULD SPEAK A LITTLE
09:53AM 13 BIT -- MS. SAHARIA WAS SUGGESTING THAT LEGAL OPINIONS, THAT
09:53AM 14 THIS WITNESS WOULD OFFER LEGAL OPINIONS. I WAS ASKING HER
09:53AM 15 ABOUT, WELL, WEREN'T THEY JUST REGULATIONS AND DOES HE HAVE TO
09:53AM 16 GIVE A LEGAL OPINION ABOUT THAT? YOU HEARD HER ANSWERS.

09:53AM 17 ANYTHING YOU WANT TO TELL ME ABOUT THAT?

09:53AM 18 MR. LEACH: HE DOES NOT HAVE TO GIVE A LEGAL OPINION
09:53AM 19 TO SAY THERANOS WAS NOT ABIDING BY THE INDUSTRY STANDARD.

09:53AM 20 THE INDUSTRY STANDARD MIGHT BE THE SAME, IT MIGHT BE
09:53AM 21 GREATER, IT MIGHT BE LESSER THAN WHAT THE LAW REQUIRES.

09:54AM 22 HE CAN GIVE WHAT IS IN THAT FIRST BUCKET, THE INDUSTRY
09:54AM 23 STANDARD, WITHOUT SAYING THAT THEY VIOLATED THE LAW OR THEY
09:54AM 24 BREACHED THIS PARTICULAR CFR.

09:54AM 25 THE COURT: SO YOUR VISION, OR WHAT I'M HEARING YOU

09:54AM 1 SAY, IS THAT HE WOULD TESTIFY ABOUT INDUSTRY STANDARDS AND TALK
09:54AM 2 ABOUT THAT, THE JURY WOULD BE INFORMED ABOUT WHAT THOSE ARE
09:54AM 3 FROM THIS WITNESS'S OPINION.

09:54AM 4 AND THEN THE QUESTION WOULD BE POSED: DID THERANOS FOLLOW
09:54AM 5 THE INDUSTRY STANDARDS THAT YOU'VE JUST INDICATED?

09:54AM 6 MR. LEACH: YES.

09:54AM 7 THE COURT: AND HE WOULD SAY YES OR NO AS TO EACH
09:54AM 8 ONE OF THOSE STANDARDS.

09:54AM 9 MR. LEACH: YES.

09:54AM 10 THE COURT: AND THAT IS NOT A LEGAL OPINION?

09:54AM 11 MR. LEACH: THAT IS NOT A LEGAL OPINION.

09:54AM 12 THE COURT: OKAY.

09:54AM 13 MR. LEACH: LET ME FRAME IT ONE MORE WAY THAT I
09:54AM 14 FOUND HELPFUL AFTER READING THE DEFENSE BRIEF.

09:54AM 15 THE COURT: SURE.

09:54AM 16 MR. LEACH: I ANTICIPATE IF WE WERE TO ASK
09:54AM 17 DR. MASTER, ASSUME THE CFR DIDN'T EXIST, ASSUME CMS WASN'T
09:55AM 18 HERE. WOULD YOU STILL DO PROFICIENCY TESTING AS A LAB
09:55AM 19 DIRECTOR? OF COURSE I WOULD DO PROFICIENCY TESTING. THAT'S
09:55AM 20 HOW WE KNOW OUR DEVICE IS GENERATING THE RIGHT RESULT. WE RUN
09:55AM 21 IT ON THIS AND WE SEND IT TO THE TESTING ENTITY AND THEY TELL
09:55AM 22 US IF WE GOT IT RIGHT.

09:55AM 23 SO IF CMS DOESN'T EXIST, IF THERE IS NO REGULATION, WOULD
09:55AM 24 YOU DO THESE THINGS? OF COURSE YOU WOULD. ANY LAB DIRECTOR
09:55AM 25 WOULD DO THOSE THINGS.

09:55AM 1 THAT'S THE INDUSTRY STANDARD THAT HE'S EMINENTLY QUALIFIED
09:55AM 2 TO TALK ABOUT.

09:55AM 3 THE COURT: OKAY. THANK YOU. THANK YOU.
09:55AM 4 MS. SAHARIA.

09:55AM 5 MS. SAHARIA: JUST A FEW MINOR POINTS.
09:55AM 6 IF THERE WAS ANYTHING THAT WAS CLEAR FROM MR. LEACH'S
09:55AM 7 PRESENTATION IS THAT DR. MASTER IN LARGE PART SIMPLY INTENDS TO
09:55AM 8 PARROT DR. ROSENDORFF. WE'VE HEARD IN A NUMBER OF DIFFERENT
09:55AM 9 AREAS THAT HIS OPINION IS BASED ON DR. ROSENDORFF'S TESTIMONY.

09:56AM 10 IT IS NOT APPROPRIATE FOR ONE EXPERT TO SIMPLY PARROT
09:56AM 11 EITHER THE FACT TESTIMONY OF DR. ROSENDORFF OR THE EXPERT
09:56AM 12 TESTIMONY OF DR. ROSENDORFF.

09:56AM 13 AGAIN, THE REASON WHY DR. MASTER IS DOING THAT IS BECAUSE
09:56AM 14 HE DOESN'T HAVE ACCESS TO DATA BECAUSE WE DON'T HAVE THE DATA.
09:56AM 15 SO HE'S BASING OPINIONS IN SOME CASES ON DR. ROSENDORFF'S
09:56AM 16 AFTER-THE-FACT IMPRESSIONS OF WHETHER THERANOS WAS CONDUCTING
09:56AM 17 PROPER PROFICIENCY TESTING, WHICH MAY NOT EVEN REFLECT
09:56AM 18 DR. ROSENDORFF'S REALTIME ASSESSMENTS.

09:56AM 19 IT IS CLEAR THAT DR. MASTER DOES INTEND TO OFFER LEGAL
09:56AM 20 OPINIONS, AND I GAVE THOSE EXAMPLES TO THE COURT WHERE HE'S
09:56AM 21 TALKING ABOUT INTERPRETATIONS OF THE LAW, WHERE HE'S TALKING
09:56AM 22 ABOUT BURDENS OF PROOF, DISPUTES BETWEEN THE FDA AND THERANOS.

09:56AM 23 THOSE ARE CLEARLY LEGAL OPINIONS, AND YOU CAN'T JUST
09:56AM 24 DIVORCE IN SOME HYPOTHETICAL WORLD THE INDUSTRY STANDARDS FROM
09:57AM 25 WHAT THEY MIGHT BE IF THERE WERE NO CMS OR CFR BECAUSE THAT'S

09:57AM 1 THE WORLD THAT HE LIVES IN AND THAT IS THE WORLD THAT HE WAS
09:57AM 2 TRAINED IN.

09:57AM 3 AND WHEN HE MOVED BEYOND THE GENERAL STATEMENT, YEAH, THE
09:57AM 4 INDUSTRY STANDARD REQUIRES US TO ENGAGE IN PROFICIENCY TESTING,
09:57AM 5 AND THE NEXT QUESTION IS, WELL, HOW DO YOU DETERMINE WHETHER
09:57AM 6 IT'S APPROPRIATE TO ENGAGE AN ALTERNATIVE PROFICIENCY TESTING,
09:57AM 7 FOR EXAMPLE?

09:57AM 8 THE ANSWER TO THAT IS, THE REGULATIONS TELL US WHEN WE CAN
09:57AM 9 ENGAGE IN AN ALTERNATIVE PROFICIENCY TESTING, AND I DISAGREE
09:57AM 10 WITH THE WAY THAT THERANOS WAS INTERPRETING THOSE REGULATIONS.
09:57AM 11 THAT'S CLEARLY A LEGAL OPINION.

09:57AM 12 THE COURT: SO, MS. SAHARIA, I'M SORRY TO INTERRUPT
09:57AM 13 YOU.

09:57AM 14 MS. SAHARIA: YES.

09:57AM 15 THE COURT: YOU HEARD MR. LEACH ANSWERING MY
09:57AM 16 QUESTION, AND I ASKED HIM AND I KIND OF PROBED HIM, SET HIM UP,
09:57AM 17 IF YOU WILL.

09:57AM 18 WHAT WOULD THE QUESTIONING BE? IS THIS A LEGAL OPINION OR
09:57AM 19 WHAT WOULD THAT QUESTIONING BE?

09:57AM 20 AND HE TOLD US THE LINE OF QUESTIONING THAT WOULD SUGGEST,
09:57AM 21 NO, I'M NOT ASKING HIM A LEGAL OPINION. I'M ASKING HIM -- HE'S
09:58AM 22 QUALIFIED TO TESTIFY ABOUT INDUSTRY STANDARDS AND HE CAN TALK
09:58AM 23 ABOUT INDUSTRY STANDARDS.

09:58AM 24 AND THEN I'LL ASK HIM, DID YOU SEE THAT IN THE THERANOS
09:58AM 25 REGIME? ANYTHING ABOUT WHAT THEY WERE DOING THAT COMPLIED WITH

09:58AM 1 OR FOLLOWED INDUSTRY STANDARDS? YES? NO?

09:58AM 2 MS. SAHARIA: SO I THINK TWO PROBLEMS WITH THAT.

09:58AM 3 THE FIRST IS THE ONE WHICH I STARTED WITH, WHICH IS HIS
09:58AM 4 ANSWERS TO THAT QUESTIONS ARE GOING TO BE BASED ENTIRELY ON HIS
09:58AM 5 PARROTING OF WHAT DR. ROSENDORFF HAS SAID ABOUT WHAT THERANOS
09:58AM 6 WAS DOING, NOT ON DR. MASTER'S OWN ANALYSIS OF ACTUAL EVIDENCE
09:58AM 7 AND DATA REGARDING WHAT THERANOS WAS DOING WITH RESPECT TO
09:58AM 8 PROFICIENCY TESTING.

09:58AM 9 BUT ON THE ISSUE OF THE LEGAL OPINION, I DON'T KNOW HOW WE
09:58AM 10 CAN CROSS-EXAMINE DR. MASTER ABOUT THAT VAGUE INDUSTRY STANDARD
09:58AM 11 OPINION WITHOUT GETTING INTO THE REGULATIONS BECAUSE THE
09:58AM 12 REGULATIONS ARE WHAT INFORM THOSE INDUSTRY STANDARDS.

09:58AM 13 HE ACKNOWLEDGES THAT IN THE BEGINNING SECTION OF HIS BRIEF
09:58AM 14 WHERE HE SAYS THAT HE LAYS OUT THE INDUSTRY STANDARDS, AND ALL
09:59AM 15 OF THOSE ARE DRAWN FROM THE CFR AND FROM CLIA.

09:59AM 16 SO I DON'T KNOW HOW -- WE CAN OFFICIALLY TALK AROUND THE
09:59AM 17 SUBJECT OF THE REGULATIONS, I SUPPOSE, WITH DR. MASTER, BUT
09:59AM 18 THAT'S ARTIFICIAL AND IT WILL HAMPER OUR ABILITY TO
09:59AM 19 CROSS-EXAMINE HIM WHEN ALL OF THOSE INDUSTRY STANDARDS ARE
09:59AM 20 BASED ON FEDERAL LAW.

09:59AM 21 THANK YOU.

09:59AM 22 THE COURT: ALL RIGHT. THANK YOU.

09:59AM 23 MR. LEACH, ANYTHING FURTHER?

09:59AM 24 MR. LEACH: NO, YOUR HONOR. THANK YOU.

09:59AM 25 THE COURT: ALL RIGHT. THANK YOU. AND THANK YOU

09:59AM 1 FOR THE CONVERSATION ON THIS.

09:59AM 2 I WILL -- THIS IS ONE THAT YOU'LL RECEIVE THE COURT'S
09:59AM 3 DECISION IN A WRITTEN ORDER. I WILL TELL YOU THAT I DO INTEND
09:59AM 4 TO SCHEDULE A DAUBERT HEARING AT SOME POINT, AND WE'LL LOOK AT
09:59AM 5 OUR CALENDARS AND WE'LL CONSULT WITH YOU AS TO WHEN THE BEST
09:59AM 6 TIME FOR THAT IS, OBVIOUSLY PRIOR TO THE PRETRIAL CONFERENCE.

09:59AM 7 MS. SAHARIA: THANK YOU, YOUR HONOR.

09:59AM 8 THE COURT: OKAY. THANK YOU.

10:00AM 9 ALL RIGHT. NEXT I BELIEVE IS DOCKET 574, MS. HOLMES'S
10:00AM 10 MOTION TO EXCLUDE EVIDENCE OF CMS SURVEY FINDINGS AND
10:00AM 11 SANCTIONS.

10:00AM 12 IT LOOKS LIKE CONCURRENT WITH THIS IS THE GOVERNMENT'S
10:00AM 13 NUMBER 6, TO ADMIT THE CMS FORM 2567.

10:00AM 14 I THINK THE CONVERSATION IS THE --

10:00AM 15 MR. LEACH: YES.

10:00AM 16 THE COURT: RIGHT.

10:00AM 17 MR. LOOBY: GOOD MORNING, YOUR HONOR. YES, I'LL BE
10:00AM 18 ADDRESSING BOTH MS. HOLMES'S MOTION TO EXCLUDE THE REPORT AND
10:00AM 19 ITS FINDINGS WITH THE CMS INSPECTIONS IN 2015 AND 2016 OF
10:00AM 20 THERANOS'S CLIA LABORATORIES.

10:00AM 21 THE GOVERNMENT'S MOTION BASICALLY DOESN'T ADDRESS ANY
10:00AM 22 ISSUES THAT ARE NOT ADDRESSED IN OUR MOTION, SO I THINK THEY
10:00AM 23 CAN BE KIND OF ADDRESSED AT THE SAME TIME.

10:00AM 24 THE COURT: ALL RIGHT. THANK YOU, MR. LOOBY.

10:00AM 25 MR. LOOBY: SO THE ISSUES THESE MOTIONS RAISE FALL

10:00AM 1 INTO TWO BUCKETS, SO THERE'S THE RELEVANCY AND THE 403 ISSUES,
10:01AM 2 AND THERE'S THE HEARSAY ISSUES WITH THE REPORTS AND THE
10:01AM 3 FINDINGS THEMSELVES.

10:01AM 4 I'LL PROPOSE ADDRESSING THEM IN THAT ORDER.

10:01AM 5 THE FIRST QUESTION, IS THE EVIDENCE RELEVANT FOR THE
10:01AM 6 PURPOSES THAT THE GOVERNMENT IS OFFERING IT?

10:01AM 7 IT MIGHT SEEM STRAIGHTFORWARD, BUT ANSWERING IT ACTUALLY
10:01AM 8 INVOLVES SOME TECHNICAL CONCEPTS AND I THINK IT'S HELPFUL TO GO
10:01AM 9 OVER WHAT A CMS ENTAILS AND WHAT IT DOESN'T ENTAIL.

10:01AM 10 SO WHAT DOES A CMS INSPECTION ENTAIL? SO AT THE HIGHEST
10:01AM 11 LEVEL, CMS INSPECTORS LOOK TO SEE WHETHER THE CLIA LAB HAS THE
10:01AM 12 SAME WRITTEN POLICIES AND PROCEDURES THAT THE REGULATIONS
10:01AM 13 REQUIRE.

10:01AM 14 AND THEY WILL LOOK FOR EVIDENCE THAT THE LAB IS COMPLYING
10:01AM 15 WITH ITS OWN PROCEDURES.

10:01AM 16 IF AN INSPECTOR FINDS THAT EITHER A REQUIRED PROCEDURE
10:01AM 17 DOESN'T EXIST OR IF THEY ENCOUNTER EVIDENCE THAT THE LAB IS NOT
10:01AM 18 FOLLOWING THEIR OWN PROCEDURES, THEY WILL MAKE A FINDING OF A
10:01AM 19 CLIA REGULATORY DEFICIENCY.

10:01AM 20 SO THESE COME IN A FEW FLAVORS. THE ENTRY LEVEL IS WHAT
10:02AM 21 IS CALLED A STANDARD LEVEL DEFICIENCY, AND A COUPLE OF STANDARD
10:02AM 22 LEVEL DEFICIENCIES CAN ESSENTIALLY ROLL UP INTO WHAT IS CALLED
10:02AM 23 A CONDITION LEVEL DEFICIENCY, AND THEN ON TOP OF THAT, THERE
10:02AM 24 COULD BE AN IMMEDIATE JEOPARDY FINDING, AND I'LL TALK MORE
10:02AM 25 ABOUT THAT LATER.

1 SO THE CLIA REGULATIONS AND THE POLICIES AND PROCEDURES
2 THEY REQUIRE, THEY REALLY RUN THE GAMUT. SO SOME ARE BASIC,
3 LIKE REQUIRING THAT THE LABORATORY HAVE ON HAND DOCUMENTATION
4 SHOWING THAT THE CLIA LAB STAFF HAVE APPROPRIATE EDUCATIONAL
5 AND EXPERIENTIAL BACKGROUND.

6 OTHERS ARE MORE TECHNICAL, AND WE DON'T NEED TO GO INTO
7 ALL OF THEM. MY COLLEAGUES AND THE GOVERNMENT ADDRESSED
8 PROFICIENCY TESTING, OR PT, IN THE LAST MOTION, SO I WON'T
9 DWELL ON THAT.

10 SECOND, THERE'S QUALITY CONTROL, OR QC. SO GENERALLY
11 SPEAKING, CLIA REGS, THEY REQUIRE LABORATORIES TO ADOPT QC
12 PROCEDURES, AND THIS INVOLVES RUNNING A CONTROL SAMPLE THROUGH
13 A LAB DEVICE ON A REGULAR BASIS AND SEEING IF YOU GET CLOSE
14 ENOUGH TO THE EXPECTED VALUE.

15 LABS ARE REQUIRED TO KEEP THEIR HISTORICAL QC DATA ON HAND
16 AND THE LAB INSPECTOR, THE CMS INSPECTOR, MIGHT ASK TO SEE THE
17 HISTORICAL QC DATA IN ADDITION TO LOOKING AT THE POLICIES AND
18 PROCEDURES THEMSELVES.

19 SO IF THE INSPECTOR SPOTS AN ISSUE WITH THE QC, THEN THEY
20 MIGHT WANT TO SEE DOCUMENTATION THAT THE LAB IDENTIFIED IT AT
21 THE TIME THAT THEY INVESTIGATED THE ISSUE AND THAT THEY SOLVED
22 THE ISSUE.

23 SO THE FINAL BUCKET OF ISSUES BEFORE WE MOVE ON IS QUALITY
24 ASSESSMENT, OR QA. AND SO THE WAY TO THINK ABOUT THIS IS THAT
25 IT SITS ON TOP OF QC, AND IT INVOLVES KIND OF A MORE HOLISTIC

10:03AM 1 REVIEW OF QC, TRANSIT OF QC DATA THAT DAILY QC MONITORING MIGHT
10:03AM 2 MISS.

10:03AM 3 THOSE ARE THE KIND OF BUCKETS.

10:03AM 4 BUT BEFORE -- ONE MORE NOTE ABOUT QC IS THAT QC DATA IS
10:03AM 5 INHERENTLY DIFFERENT FROM PATIENT RESULTS. THE QC CONTROL
10:03AM 6 SAMPLE THAT IS RUN THROUGH THE LAB'S DEVICE IS AN SYNTHETIC
10:04AM 7 MATERIAL THAT CLIA LABS CAN BUY FROM LAB SUPPLY COMPANIES.

10:04AM 8 IN OTHER WORDS, IN REVIEWING THE QC DATA, THE CMS
10:04AM 9 INSPECTOR IS NOT LOOKING AT PATIENT RESULTS.

10:04AM 10 LIKEWISE, THE COEFFICIENT OF VARIATION, OR CV PERCENTAGE,
10:04AM 11 WHICH YOU'LL SEE IN THE CMS REPORT AND ON WHICH DR. MASTER
10:04AM 12 RELIES TO EXTRAPOLATE HIS OPINIONS, THIS IS A STATISTICAL
10:04AM 13 FIGURE IN THIS INSTANCE BASED ON QC DATA AND NOT PATIENT
10:04AM 14 RESULTS.

10:04AM 15 THE SECOND THING TO KEEP IN MIND ABOUT QC IS THAT IT DOES
10:04AM 16 NOT NECESSARILY MEAN THAT THERE'S AN ISSUE WITH THE DEVICE IF
10:04AM 17 THERE'S A QC FAILURE.

10:04AM 18 THERE'S A COUPLE OF REASONS WHY THAT IS. IT COULD BE THAT
10:04AM 19 THERE'S AN ISSUE WITH THE QC MATERIAL THAT IS RUN, LIKE IT WAS
10:04AM 20 STORED IMPROPERLY.

10:04AM 21 OR IT COULD SIGNIFY THAT THERE'S AN ISSUE WITH THE REAGENT
10:04AM 22 USED IN THE TEST, AND AT ITS MOST SIMPLE LEVEL, IT COULD JUST
10:04AM 23 BE CHALKED UP TO HUMAN ERROR.

10:04AM 24 SO HERE'S AN EXAMPLE OF HOW THIS COULD OCCUR. SO IT'S
10:04AM 25 HELPFUL TO THINK ABOUT IT. SO QC CONTROL SAMPLES OFTEN COME IN

10:05AM 1 VERY LOW CONCENTRATIONS AND VERY HIGH CONCENTRATIONS, AND THIS
10:05AM 2 IS DESIGNED TO TEST THE PERFORMANCE OF THE TEST AT THE
10:05AM 3 EXTREMES.

10:05AM 4 AND SO A LAB TECHNICIAN COULD MISTAKENLY RUN THE HIGH
10:05AM 5 SAMPLE WHEN THE MACHINE IS PRIMED TO ACCEPT THE LOW SAMPLE AND
10:05AM 6 THIS WOULD RESULT IN A VERY ERRANT DATA POINT. THE TECHNICIAN
10:05AM 7 WOULD PROBABLY FIGURE THIS OUT WHEN LOOKING AT IT AND SAY,
10:05AM 8 OKAY, I KIND OF KNOW WHAT IS GOING ON HERE.

10:05AM 9 BUT THAT RESULT WILL STILL BE LOGGED IN THE MACHINE'S
10:05AM 10 HISTORICAL QC DATA WHEN AN INSPECTOR COMES IN AND ASKS TO SEE
10:05AM 11 THE RECORDS.

10:05AM 12 AND IF THAT TECHNICIAN, AFTER KIND OF FIGURING OUT WHAT
10:05AM 13 WENT WRONG, DOESN'T DOCUMENT WHAT HAPPENED, THEN IT COULD LOOK
10:05AM 14 YEARS LATER IN RETROSPECT LIKE THE LAB WAS IGNORING QC FAILURES
10:05AM 15 AND CONTINUING TO RUN PATIENT SAMPLES WITHOUT ADDRESSING KIND
10:05AM 16 OF WHAT THE ROOT CAUSE OF THE QC IS, WHEN THAT ACTUALLY ISN'T
10:05AM 17 THE CASE.

10:05AM 18 SO I THINK TAKING A STEP BACK, THE BEST WAY TO THINK ABOUT
10:05AM 19 LIKE A QC FAILURE, IT'S LIKE A RED FLAG OR AN INDICATOR THAT
10:06AM 20 SOMETHING IS AWRY, BUT IT ITSELF DOESN'T REALLY TELL US
10:06AM 21 ANYTHING ABOUT KIND OF WHAT IS UP. IT'S UP TO THE CLIA LAB TO
10:06AM 22 FOLLOW ITS PROCEDURES, WHICH ARE USUALLY OUTLINING THE STEPS
10:06AM 23 YOU WOULD TAKE TO INVESTIGATE THAT.

10:06AM 24 SO HERE'S WHAT THE INSPECTOR DOESN'T LOOK AT. THE CMS
10:06AM 25 INSPECTOR DOESN'T LOOK AT OR ANALYZE PATIENT DATA.

1 AND THIS IS WHAT THE CMS INSPECTOR, SARAH BENNETT, TOLD
2 THE GOVERNMENT, AND THIS IS AT DEFENSE EXHIBIT 34 AND IT'S HER
3 2017 GOVERNMENT INTERVIEW MEMORANDUM.

4 IT DOESN'T ISSUE FINDINGS THAT THE PATIENT TEST RESULTS
5 WERE INACCURATE OR UNRELIABLE, AND WHILE A CMS LAB INSPECTOR
6 MIGHT CITE A LAB FOR POOR QC PRACTICES, IT DOESN'T TAKE THAT
7 EXTRA STEP OF DIAGNOSING THE QC FAILURE.

8 IT ALSO DOESN'T MAKE A FINDING THAT PATIENT RESULTS
9 ACTUALLY HAVE BEEN IMPACTED BY ANY DEFICIENCIES, INCLUDING FOR
10 QC ISSUES.

11 EVEN AN IMMEDIATE JEOPARDY FINDING, WHICH IS THE MOST
12 SEVERE FINDING THAT A CMS INSPECTOR CAN MAKE, IT'S NOT A
13 FINDING THAT PATIENT HEALTH HAS ACTUALLY BEEN IMPACTED. IF YOU
14 LOOK AT THE REGULATORY TEXT -- AND WE'LL PULL UP THE CMS LATER
15 THAT HAS THE TEXT IN IT -- BUT IT'S A FINDING THAT THERE'S A
16 SUFFICIENT RISK THAT PATIENT RESULTS COULD BE IMPACTED SUCH
17 THAT IMMEDIATE ACTION IS REQUIRED FROM THE LAB.

18 SO THERE'S A REASON WHY CMS DOESN'T DO THESE THINGS. THE
19 REGULATORY SCHEME PUTS THE BURDEN ON THE LAB COMPANY, NOT THE
20 REGULATOR, TO PROVE THE NEGATIVE.

21 IN THE WORDS OF CMS WITNESS SARAH BENNETT, IT'S NOT CMS'S
22 JOB TO DO THAT FOR THE LAB COMPANY.

23 SO INSTEAD THE LAB MUST PROVE FOR ANY DEFICIENCY THAT IT
24 IDENTIFIED THE PROBLEM AT THE TIME, THAT IT HAS THE RECORDS TO
25 SHOW THAT IT COULD LOOK AND SAY PATIENT RESULTS WERE NOT

10:07AM 1 IMPACTED.

10:07AM 2 THIS BURDEN SHIFTING PARADIGM, PERHAPS IT MAKES SENSE IN
10:08AM 3 THE CIVIL REGULATORY CONTEXT, YOU KNOW, DEFICIENCY, WE PASS THE
10:08AM 4 BALL TO YOU, THE LAB. YOU TELL US THAT NO PATIENT RESULTS WERE
10:08AM 5 IMPACTED, AND IF YOU CAN'T PROVE THAT WITH DOCUMENTATION, THEN
10:08AM 6 THE OBSERVATION IS GOING TO BE TURNED INTO A POTENTIAL PENALTY.

10:08AM 7 BUT THAT BURDEN SHIFTING PARADIGM IS AT THE HEART OF WHY
10:08AM 8 THE GOVERNMENT'S PROPOSED USE OF THE CMS REPORT IS SO
10:08AM 9 PROBLEMATIC IN THIS CRIMINAL CASE.

10:08AM 10 SO THAT LEADS US TO THE GOVERNMENT'S RELEVANCE THEORY.
10:08AM 11 THE GOVERNMENT ARGUES THAT THE CMS INSPECTION FINDINGS, THEY
10:08AM 12 TEND TO SHOW THE ACCURACY AND RELIABILITY ISSUES WITH
10:08AM 13 THERANOS'S TECHNOLOGY.

10:08AM 14 THEIR OPPOSITION BRIEF EVEN GOES SO FAR AS TO CLAIM THAT
10:08AM 15 THE REPORT, QUOTE, PUTS THE LIE TO THE DEFENDANT'S GRANDIOSE
10:08AM 16 CLAIMS ABOUT THERANOS'S TECHNOLOGY, AND THAT'S AT THE
10:08AM 17 OPPOSITION BRIEF TO OUR MOTION IN LIMINE AT PAGE 2.

10:08AM 18 BUT AS WE JUST WALKED THROUGH, CMS ACTUALLY DIDN'T MAKE
10:08AM 19 ANY FINDINGS ABOUT THERANOS'S TECHNOLOGY OR THE ACCURACY OR
10:08AM 20 RELIABILITY OF ANY OF ITS TESTS. SO THAT'S AN ISSUE AT THE
10:09AM 21 START FOR THE GOVERNMENT'S THEORY.

10:09AM 22 THE GOVERNMENT ALSO RELIES VERY HELPFUL ON ISSUES WITH QC
10:09AM 23 AND HOLDS THEM OUT AS SELF-EVIDENT ISSUES UNDERLYING THE
10:09AM 24 TECHNOLOGY.

10:09AM 25 AS WE JUST DISCUSSED, THE QC CITATIONS IN THE REPORT MAKE

1 NO CLAIMS ABOUT THE ACTUAL PERFORMANCE OF THE TESTS.

2 NOW, THE GOVERNMENT DID DISCLOSE AN EXPERT WITNESS,
3 STEPHEN MASTER, WHO MY COLLEAGUE, MS. SAHARIA, JUST DISCUSSED,
4 TO LOOK AT THE QC CITATIONS IN THE CMS REPORT AND TRY TO
5 APPLY -- TO LOOK AT THE QC CITATIONS IN THE CMS REPORT AND
6 BASED ON HIS EXPERTISE TO EXTRAPOLATE FROM THEM ABOUT WHAT HE
7 THINKS PERHAPS THE QC CITATIONS SAY ABOUT THERANOS'S TESTS AND
8 THEIR PERFORMANCE.

9 HE COULDN'T FOR THE MOST PART, AS MS. SAHARIA EXPLAINED,
10 AND MS. SAHARIA EXPLAINED THE ISSUES WITH HIS OPINION THAT HE
11 DID OFFER.

12 BUT IN ANY EVENT, THE GOVERNMENT'S EXPERT DISCLOSURE ON
13 THIS ISSUE IS A CONCESSION THAT THE CMS REPORT AND THE QC
14 FINDINGS WITHIN IT, THEY DON'T SPEAK FOR THEMSELVES, AND THEY
15 DON'T TRANSLATE WITHOUT SOMEONE TO BRIDGE THAT CONCEPTUAL GAP
16 BETWEEN WHAT INPUTS WENT INTO THE CLIA REVIEW AND HOW THE
17 GOVERNMENT WANTS TO USE IT, WHICH IS EVIDENCE OF INACCURACY AND
18 UNRELIABILITY.

19 THE GOVERNMENT ALSO ASSERTS -- THEY TRY TO TURN IT AROUND
20 AND SAY, WELL, THERANOS EITHER AGREED WITH THE CITATIONS OR
21 DIDN'T CONTEST THEM, BUT THAT'S NOT EXACTLY TRUE.

22 IN ANY EVENT, BECAUSE THE FINDINGS DID NOT REACH THE
23 CONCLUSION ON ACCURACY AND RELIABILITY, EVEN IF THERANOS HAD
24 NOT CONTESTED ANY OF THE FINDINGS IN THE JANUARY 2016 REPORT,
25 IT STILL WOULDN'T BE A REPRESENTATION OR A CONCESSION FROM

1 THERANOS THAT THERE WERE ACCURACY OR RELIABILITY ISSUES WITH
2 PATIENT TEST REPORTS THAT WERE REPORTED.

3 SECOND, THERANOS DID REPORT TO CMS THAT, BASED ON ITS
4 HOLISTIC REVIEW, IT FOUND THAT ITS PRIOR QC AND Q/A PROCEDURES
5 AS A WHOLE WERE LACKING, AND IN RESPONSE TO THE CITATIONS WAS
6 FORWARD LOOKING AND IN A DIALOGUE WITH THE REGULATOR.

7 BUT IT'S IMPORTANT TO KEEP IN MIND THE BALL AT THAT TIME
8 WAS IN THERANOS'S COURT TO PROVE THE NEGATIVE.

9 THE JANUARY 2016 REPORT IS KIND OF THE OPENING
10 COMMUNICATION IN A BACK AND FORTH IN WHICH THERE'S AN
11 OPPORTUNITY TO EITHER KIND OF CONTEST THE CITATIONS OR TO
12 EXPLAIN TO THE REGULATOR KIND OF THIS IS HOW WE'RE IMPROVING
13 GOING FORWARD.

14 SO THAT'S ONE REASON WHY PUTTING THIS CMS REPORT, WHICH
15 HAS THESE KIND OF HEARSAY OBSERVATIONS FROM THE INSPECTOR,
16 SOMETIMES MULTIPLE LEVELS OF HEARSAY BECAUSE THE FINDINGS
17 THEMSELVES, THEY WILL INCORPORATE INFORMATION THAT WAS RELAYED
18 TO THE INSPECTOR FROM CLIA LAB STAFF, USUALLY NOT NAMED.

19 THAT'S WHY IT'S SO DANGEROUS TO KIND OF PUT THAT BEFORE
20 THE JURY WITHOUT THE AID OF AN EXPERT OPINION AND JUST SAY,
21 LOOK, HERE'S WHAT THE CMS FOUND, IT FOUND THAT THERE WERE QC
22 VIOLATIONS ON THESE WEEKS ON THESE TESTS. JURY, WE'RE ASKING
23 YOU TO FIND THAT THIS IS EVIDENCE OF INACCURACY AND
24 UNRELIABILITY.

25 AND THE JURY IS JUST NOT EQUIPPED TO DO THAT ON ITS OWN.

1 THE EVIDENCE DOESN'T QUITE REACH THAT LEVEL THAT THE GOVERNMENT
2 WOULD HAVE IT, AND IT'S JUST GOING TO CONFUSE THE ISSUES.

3 AND THE REASON FOR THAT IS BECAUSE THE INSPECTION, BY
4 DESIGN, STOPPED SHORT OF REACHING THE TYPE OF CONCLUSION THAT
5 THE GOVERNMENT CLAIMS IT WOULD SHOW.

6 I THINK THE BEST EVIDENCE FOR THIS IS GOVERNMENT WITNESS
7 SARAH BENNETT. SO SHE EXPLAINED THAT TO THE GOVERNMENT IN
8 2017, SHE SAID -- AND I'M PARAPHRASING -- WE AREN'T IN THE
9 BUSINESS OF MAKING THAT TYPE OF FINDING.

10 THE GOVERNMENT WENT BACK TO HER IN 2020 WHEN OUR MOTION
11 WAS PENDING AND SHE TOLD THEM KIND OF THE BASICALLY SAME THING.
12 THAT'S AT GOVERNMENT'S EXHIBIT 24, ECF 680-10.

13 THE TAKEAWAY FROM HER STATEMENTS TO THE GOVERNMENT IS THAT
14 CMS DOESN'T MAKE ACCURACY AND RELIABILITY FINDINGS. FULL STOP.

15 THE GOVERNMENT'S EFFORT TO FLATTEN THIS DISTINCTION AND
16 PUT THE REPORT INTO EVIDENCE IS GOING TO ASK THE JURY TO MAKE A
17 CONNECTION THAT ITS OWN WITNESS WOULD NOT.

18 THE PREJUDICE FROM THIS EVIDENCE STEMS FROM THE
19 INTERSECTION OF TWO CONCEPTS, ONE OF WHICH IS A CONCEPT THAT
20 YOU HAD ADDRESSED IN DIALOG WITH MY COLLEAGUE, MR. FLEURMONT,
21 YESTERDAY ABOUT CAN A CIVIL REGULATORY VIOLATION AND EVIDENCE
22 OF THAT COMING IN AND KIND OF CONFUSING THE ISSUES AND
23 ENCOURAGING THE JURY TO THINK, WELL, THE GOVERNMENT FOUND THAT
24 THERE WERE SOME VIOLATIONS OF LAWS THAT VAGUELY HAVE TO DO WITH
25 LAB PERFORMANCE OR LAB HYGIENE, AND SO THE GOVERNMENT MUST HAVE

10:13AM 1 AGREED WITH THE GOVERNMENT'S ALLEGATIONS HERE THAT THE TEST
10:14AM 2 RESULTS WERE INACCURATE AND UNRELIABLE.

10:14AM 3 SO A GOOD CITATION FOR THAT KIND OF PREJUDICE IS U.S. V.
10:14AM 4 WOLF, WHICH WAS ADDRESSED YESTERDAY, AND THAT'S AT 820 F.2D
10:14AM 5 1499.

10:14AM 6 BUT HERE THE GOVERNMENT REPORT, YOU KNOW, IS EVEN MORE
10:14AM 7 PREJUDICIAL BECAUSE IT GIVES THE GOVERNMENT IMPRIMATUR TO THE
10:14AM 8 GOVERNMENT -- THE GOVERNMENT AGENCY IMPRIMATUR TO THE
10:14AM 9 GOVERNMENT, THE U.S. ATTORNEY'S OFFICE'S, ALLEGATIONS IN THIS
10:14AM 10 CASE.

10:14AM 11 SO THOSE ARE KIND OF THE RELEVANCY AND THE 403 ISSUES.

10:14AM 12 I CAN PROCEED TO THE HEARSAY ISSUES UNLESS YOUR HONOR HAS
10:14AM 13 QUESTIONS.

10:14AM 14 THE COURT: NO. LET'S TALK ABOUT THIS. AND THIS IS
10:14AM 15 A DISCUSSION I THINK ABOUT 803(8) AND WHETHER THIS IS DOUBLE I
10:14AM 16 OR TRIPLE I.

10:14AM 17 MR. LOOBY: RIGHT. SO ACTUALLY THE GOVERNMENT MAKES
10:14AM 18 A COUPLE OF CONCESSIONS IN ITS BRIEFING THAT I THINK ARE
10:14AM 19 IMPORTANT TO PUT ON THE TABLE AT THE START.

10:15AM 20 SO THE GOVERNMENT DOESN'T CONTEST THAT 803(6), THE
10:15AM 21 BUSINESS RECORDS EXCEPTION, IS AVAILABLE TO THEM. BECAUSE
10:15AM 22 THESE ARE PUBLIC RECORDS, THE NINTH CIRCUIT HAS HELD THAT WE'RE
10:15AM 23 IN 803 LAND, 803(8) LAND.

10:15AM 24 SO THE GOVERNMENT ALSO DOES NOT CONTEST THAT 803(8) (A) (3)
10:15AM 25 REPORTS FROM GOVERNMENT INVESTIGATIONS, DOESN'T APPLY, THAT THE

1 REPORT COULD BE ADMISSIBLE UNDER THAT PROVISION.

2 THE GOVERNMENT CONCEDES THIS BY BASICALLY NOT ADDRESSING
3 OUR ARGUMENTS IN OUR MOTION REGARDING THAT SUBSECTION. INSTEAD
4 THE GOVERNMENT IS RELYING SOLELY ON SUBSECTION (A) (2), THE
5 MATTERS OBSERVED OR A DUTY TO REPORT.

6 SO WE HAVE TWO WAYS IN WHICH THE GOVERNMENT'S RELIANCE ON
7 (A) (2) KIND OF FAILS, AND ONE OF THEM IS RIGHT OUT OF THE GATE,
8 (A) (2) IS NOT AVAILABLE TO THEM, AND THAT'S BECAUSE WHEN
9 THERE'S A PIECE OF EVIDENCE THAT CONCEDEDLY, AS HERE,
10 CONCEDEDLY IS NOT ADMISSIBLE UNDER (A) (3), (A) (2) DOES NOT
11 PROVIDE THE GOVERNMENT A SECOND BITE AT THE APPLE.

12 SO THE BEST CASE FOR THAT THAT WE WERE ABLE TO FIND, AND I
13 THINK THE ONLY CASE THAT EITHER SIDE CITED THAT ADDRESSED THIS
14 ISSUE SQUARELY WAS THE MURGIO DECISION OUT OF THE SOUTHERN
15 DISTRICT OF NEW YORK -- M-U-R-G-I-O -- AND THAT'S A 2017
16 OPINION BY JUDGE NATHAN IN THE SOUTHERN DIRECT. THE MURGIO
17 CASE LOOKED AND STARTED WITH THE TEXT OF THE RULE AND I THINK
18 THAT'S HELPFUL.

19 MS. SAHARIA, IF YOU COULD PULL UP THE RULE DEMONSTRATIVE.

20 WHILE SHE'S PULLING THAT UP, WHAT THIS IS, IS RULE 803(8).

21 ALL RIGHT. AS WE WERE TALKING, WE'RE DEALING WITH
22 SUBSECTION (2) AND SUBSECTION (3). SO A HELPFUL CANON OF
23 STATUTORY INTERPRETATION, WHICH IS ESSENTIALLY WHAT WE'RE DOING
24 HERE, IT'S KIND OF THE RULE AGAINST REDUNDANCY AND WHETHER OR
25 NOT A BROADER SUBSECTION WILL SUBSUME WITHIN A MORE SPECIFIC

10:17AM 1 SUBSECTION.

10:17AM 2 SO AS IT APPLIES HERE, THE QUESTION BECOMES, IS EVERY
10:17AM 3 INSTANCE OF AN (A) (3), A GOVERNMENT REPORT FROM A LEGALLY
10:17AM 4 AUTHORIZED INVESTIGATION, WOULD THAT BE SUBSUMED WITHIN (A) (2)?
10:17AM 5 ARE THOSE ALL MATTERS REPORTED BY A GOVERNMENT AGENT WHEN THEY
10:17AM 6 ARE UNDER A DUTY TO REPORT?

10:17AM 7 I THINK THE ANSWER TO THAT HAS TO BE YES, AND THIS IS KIND
10:17AM 8 OF WHAT MURGIO, THE MURGIO COURT WALKS THROUGH.

10:17AM 9 SO THE SCOPE OF (A) (2) HAS BEEN READ TO INCLUDE, YOU KNOW,
10:17AM 10 ROUTINE MATTERS REPORTED BY PUBLIC OFFICIALS IN THE SCOPE OF
10:17AM 11 THEIR EMPLOYMENT. IT'S A LITTLE BIT LIKE KIND OF THE BUSINESS
10:18AM 12 RECORDS EXCEPTION, BUT FOR GOVERNMENT RECORDS.

10:18AM 13 NOW, WHEN A GOVERNMENT ENTITY CONDUCTS A LEGALLY
10:18AM 14 AUTHORIZED INVESTIGATION AND IT GENERATES A REPORT OF THAT WITH
10:18AM 15 ITS FINDINGS, IT'S BY DEFINITION A MATTER REPORTED WHILE THAT
10:18AM 16 AGENT WAS UNDER AN OBLIGATION TO REPORT.

10:18AM 17 SO SUBSECTION (3), I THINK THE BEST WAY TO THINK OF IT IS
10:18AM 18 IT'S A SPECIAL APPLICATION OF SUBSECTION (2).

10:18AM 19 AND THE GOVERNMENT ARGUES THAT THIS READING -- THEIR
10:18AM 20 STATUTORY INTERPRETATION ARGUMENT IS BASICALLY READING THE WORD
10:18AM 21 "OR" OUT OF THE RULE.

10:18AM 22 BUT JUST BECAUSE IT HAS THE WORD "OR" DOES NOT MEAN IT HAS
10:18AM 23 TO BE READ IN THE SUBJUNCTIVE. IN FACT, I THINK THE MURGIO
10:18AM 24 COURT IS VERY PERSUASIVE THAT IN ORDER TO READ THIS COHERENTLY,
10:18AM 25 AND WHEN YOU LOOK AT THE DIFFERENT CATEGORIES, IT HAS TO BE THE

1 CASE THAT SUBSECTION (3) IS KIND OF A SPECIAL APPLICATION, IT
2 HAS A SPECIAL MORE KIND OF BLANKET RESTRICTION ON THE USE
3 AGAINST CRIMINAL DEFENDANTS, AND IT REALLY WOULD DO HARM TO THE
4 SCHEME THAT THEY'VE SET OUT HERE TO ALLOW THE GOVERNMENT TO
5 SAY, OH, WELL, IT'S REALLY -- YES, IT'S A REPORT OFFERED
6 AGAINST A CRIMINAL DEFENDANT, BUT IT'S ALSO A MATTER OBSERVED
7 UNDER AN OBLIGATION REPORT. OF COURSE IT IS.

8 BUT EVEN IF, YOU KNOW, WE ACCEPT FOR THE SAKE OF ARGUMENT
9 THAT (2) IS THEORETICALLY AVAILABLE, THERE'S STILL TWO REASONS
10 WHY THIS REPORT DOES NOT FIT THERE AND THE FACTS HERE DON'T
11 ALLOW FOR IT.

12 WE ASK, YOU KNOW, WERE THE RECORDS MADE BY LAW ENFORCEMENT
13 AND SO THERE'S THE LAW ENFORCEMENT EXCEPTION, AND ARE THEY
14 REPORTING KIND OF ROUTINE, MINISTERIAL OBJECTIVE FACTS, OR DO
15 THEY INCLUDE OBSERVATIONS, CONCLUSIONS, SUMMARIES, KIND OF
16 HIGHER LEVEL THINKING FROM THE GOVERNMENT AGENT?

17 SO TAKING THEM IN THAT ORDER, THE CMS INSPECTORS, AND CMS
18 GENERALLY, IS PROPERLY CONSIDERED LAW ENFORCEMENT WITHIN THE
19 MEANING OF 803(8), AND THE GOVERNMENT CASES EMBRACE THE IDEA
20 THAT ONE DIVIDING LINE IS WHETHER OR NOT THE REGULATORY SCHEME
21 THAT THE AGENCY IS OVERSEEING INVOLVED A POTENTIAL FOR CRIMINAL
22 LIABILITY.

23 SO THAT'S THE HANSON CASE OUT OF THE SEVENTH CIRCUIT.
24 THAT'S THE BUILDING INSPECTOR CASE. AND THE DECISION THERE,
25 THEY RULED THAT THE BUILDING INSPECTOR WAS NOT LAW ENFORCEMENT,

10:20AM 1 AND THE CRITICAL FACT THERE WAS THEY SAID, WELL, YOU COULD GET
10:20AM 2 A CIVIL FINE, BUT YOU COULD NEVER GET IN CRIMINAL HOT WATER
10:20AM 3 FROM THE BUILDING INSPECTOR AND SO THEY'RE NOT LAW ENFORCEMENT.

10:20AM 4 BUT CMS, THERE ARE CRIMINAL SANCTIONS AVAILABLE FOR
10:20AM 5 INTENTIONAL VIOLATIONS OF CMS. AND WHILE MANY OF THE SANCTIONS
10:20AM 6 ARE CIVIL IN NATURE, AT LEAST THEY START THAT WAY AND THAT'S
10:20AM 7 THE ROUTINE, CMS IS MORE LIKE AN AGENCY THAT STRADDLES THAT
10:20AM 8 KIND OF CRIMINAL/CIVIL DIVIDE, LIKE THE I.R.S. OR LIKE THE
10:20AM 9 IMMIGRATION OFFICERS THAT HAVE BEEN HELD IN THE NINTH CIRCUIT
10:20AM 10 AND IN OTHER CIRCUITS TO BE LAW ENFORCEMENT WITHIN THE MEANING
10:20AM 11 OF THE RULE.

10:20AM 12 THE COURT: DEPENDING ON WHAT THEY'RE DOING.

10:20AM 13 MR. LOOBY: RIGHT.

10:20AM 14 THE COURT: DEPENDING ON WHAT THEIR CONDUCT IS?

10:21AM 15 MR. LOOBY: ABSOLUTELY, YOUR HONOR.

10:21AM 16 THERE'S KIND OF THE FIRST QUESTION OF, ARE THEY LAW
10:21AM 17 ENFORCEMENT? AND THEN THERE'S THE SECOND QUESTION WHICH KIND
10:21AM 18 OF LOOPS BACK TO THE INQUIRY ABOUT ARE THESE ROUTINE
10:21AM 19 OBSERVATIONS OR IS THIS ADVERSARIAL?

10:21AM 20 THE COURT: SO LICENSE PLATE READING, I THINK THAT'S
10:21AM 21 OROZCO.

10:21AM 22 MR. LOOBY: RIGHT. OROZCO IS THE LICENSE PLATE, AND
10:21AM 23 KIND OF A PARADIGMATIC EXAMPLE. THERE'S HERNANDEZ-ROJAS OUT OF
10:21AM 24 THE NINTH CIRCUIT AS WELL, AND THAT INVOLVES A RECORDATION OF
10:21AM 25 LIKE A DATE OF REMOVAL, KIND OF JUST -- OR ENTRY. I FORGET

10:21AM 1 WHICH WAY IT IS IN THAT CASE.

10:21AM 2 THE COURT: IT'S --

10:21AM 3 MR. LOOBY: IT'S A BORDER CROSSING.

10:21AM 4 YOU KNOW, THIS IS ENTIRELY DIFFERENT AND SUBJECTIVITY IS
10:21AM 5 BAKED INTO THE CMS REPORT FROM THE START FOR ALL OF THE REASONS
10:21AM 6 THAT WE DISCUSSED.

10:21AM 7 THE COURT: PARDON ME. WHEN I LOOK AT THIS, WE
10:21AM 8 THINK -- WHEN IT TALKS ABOUT LEGAL OBLIGATIONS, IT'S REALLY,
10:21AM 9 DRILLING DOWN, YOU CAN'T HAVE LAW ENFORCEMENT WHO RESPOND TO A
10:21AM 10 CRIME SCENE AND DO THEIR REPORTS, THAT'S -- YOU CAN'T HAVE THAT
10:22AM 11 COME IN. THAT'S A POLICE REPORT. THAT'S A CLASSIC POLICE
10:22AM 12 REPORT, AND THAT SHOULD NOT COME IN BECAUSE THAT'S -- YOU'VE
10:22AM 13 GOT ALL KINDS OF PROBLEMS WITH IT. IT'S DONE IN THE
10:22AM 14 INVESTIGATION OF THE PROSECUTION.

10:22AM 15 MR. LOOBY: RIGHT.

10:22AM 16 THE COURT: AND I THINK EVERYBODY RECOGNIZES THAT.
10:22AM 17 THE GOVERNMENT RECOGNIZES THAT THAT'S NOT PROPER.

10:22AM 18 BUT HERE, THIS IS DIFFERENT. OF COURSE IT'S DIFFERENT.

10:22AM 19 ONE OF THE QUESTIONS IS, AND I THINK MAYBE YOU'RE ALLUDING
10:22AM 20 TO THAT NOW, IS ARE THESE -- IS CMS, ARE THESE PEOPLE LAW
10:22AM 21 ENFORCEMENT? ARE THEY LEGAL AUTHORITY?

10:22AM 22 THEY DO HAVE LEGAL AUTHORITY BASED ON THEIR JOB
10:22AM 23 DESCRIPTIONS, THE WORK THAT THEY DO, THEY HAVE SOME REGULATORY.
10:22AM 24 BUT ARE THEY REALLY -- ARE THEY LAW ENFORCEMENT OR DO THEY HAVE
10:22AM 25 AN OBLIGATION, A LEGAL OBLIGATION TO REPORT BECAUSE OF THE

1 NATURE OF THEIR TASK AND THEIR CHARGE? DO I NEED TO CONSIDER
2 THAT? IS THAT SOMETHING TO LOOK AT?

3 MR. LOOBY: WELL, I THINK THEY ARE LAW ENFORCEMENT
4 WHO HAVE -- IT'S CONJUNCTIVE. IT'S, IN SUBSECTION (2), AN
5 AGENT WHO HAS A LEGAL OBLIGATION TO REPORT, BUT NOT LAW
6 ENFORCEMENT WHEN OFFERED AGAINST A CRIMINAL DEFENDANT.

7 SO CMS, I THINK -- AND THIS IS ASSUMING THAT (A) (2) IS
8 EVEN AVAILABLE -- IT IS PROPER TO THINK OF THEM AS LAW
9 ENFORCEMENT IN THIS SETTING, AND THE GOVERNMENT'S BRIEFING I
10 THINK SAYS, OH, THE CMS REPORT WAS NOT PREPARED IN ANTICIPATION
11 OF THE LITIGATION, OR SOMETHING ALONG THOSE LINES.

12 BUT OF COURSE IT WAS, BECAUSE THIS WAS A FOR CAUSE
13 INSPECTION IN ADDITION TO KIND OF A ROUTINE CERTIFICATION, AND
14 AS YOU DISCUSSED EARLIER, IT WAS THE FEDERAL AGENCY THAT CAME
15 IN AND TOOK OVER CONTROL OF WHAT WOULD BE A NORMAL
16 CERTIFICATION, AND THAT WAS BASED BOTH ON -- ACCORDING TO
17 SARAH BENNETT, BOTH ON COMPLAINTS THAT THE AGENCY HAD RECEIVED
18 BASED ON THE ATTENTION THAT THE COMPANY HAD BEEN RECEIVING IN
19 THE MEDIA AND THAT'S WHAT SHE TOLD THE GOVERNMENT.

20 THE COURT: SO WE'RE IN THE NINTH CIRCUIT AND
21 FRYBERG TEACHES US SOMETHING ABOUT THIS AREA, DOESN'T IT? IT
22 TAKES THE DISTINCTION FROM THE SECOND CIRCUIT, I BELIEVE.
23 ISN'T FRYBERG A LITTLE MORE LIMITING?

24 MR. LOOBY: THE GOVERNMENT CITES FRYBERG FOR THE
25 PROPOSITION THAT THE NINTH CIRCUIT, THE LAW ENFORCEMENT

10:24AM 1 EXCEPTION IS MORE LIMITED IN THE NINTH CIRCUIT THAN ELSEWHERE,
10:24AM 2 AND THAT LANGUAGE GOES ALL OF THE WAY BACK TO OROZCO IN THE
10:24AM 3 '70S, AND AT THAT TIME THE NINTH CIRCUIT WAS, FROM WHAT I
10:24AM 4 UNDERSTAND BASED ON MY RESEARCH, WAS KIND OF AT THE FOREFRONT
10:24AM 5 OF ASKING THAT FOLLOW-UP QUESTION. IT WAS, LIKE, WE DON'T END
10:24AM 6 THE INQUIRY AT, ARE THEY LAW ENFORCEMENT? WE ASK, OKAY, IS
10:24AM 7 THIS IMMIGRATION OFFICER, OKAY, THEY ARE LAW ENFORCEMENT, BUT
10:24AM 8 ARE THEY ENFORCING THE LAW AT THIS TIME? IS THIS A SUBJECTIVE
10:24AM 9 ADVERSARIAL PROCEEDING OR ARE THEY JUST STAMPING A PASSPORT?

10:24AM 10 AND AT THE TIME THE NINTH CIRCUIT WAS KIND OF AT THE
10:24AM 11 FOREFRONT OF THAT UNDER THE NEW RULES OF TRACING KIND OF WHAT
10:24AM 12 WAS THE COMMON LAW EXCEPTION TO WHAT ENDED UP BEING IN THE
10:25AM 13 FEDERAL RULES OF EVIDENCE.

10:25AM 14 THE OTHER CIRCUITS HAVE CAUGHT UP, AND SO THE SEVENTH
10:25AM 15 CIRCUIT ASKS THESE SAME QUESTIONS THESE DAYS. IT DOESN'T SAY,
10:25AM 16 OH, LAW ENFORCEMENT. WE ASK, ARE THEY LAW ENFORCEMENT? AND
10:25AM 17 THEN WE DON'T ASK ABOUT, WELL, IS THIS A ROUTINE OBSERVATION
10:25AM 18 THAT THEY MADE KIND OF JUST COMING IN AND DOING PAPERWORK, OR
10:25AM 19 ARE THEY OUT IN THE FIELD, ARE THEY INVESTIGATING, ARE THEY
10:25AM 20 USING THE PROFESSIONAL JUDGMENT? IS ANOTHER CASE, ANOTHER KIND
10:25AM 21 OF PRINCIPAL THAT YOU SEE INFLUENCING THE LAW?

10:25AM 22 AND THAT'S WHAT THE CMS INSPECTORS WERE DOING BECAUSE THEY
10:25AM 23 WENT IN AND WERE LOOKING AND THEY HAD A FEW THINGS THAT THEY
10:25AM 24 WANTED TO LOOK AT. THEY KIND OF RECOGNIZED THAT THEY WERE
10:25AM 25 GOING TO WRITE A REPORT THAT COULD LEAD TO, YOU KNOW, A BACK

10:25AM 1 AND FORTH, A DIALOGUE WITH THE REGULATED ENTITY THAT WOULD, THE
10:25AM 2 NEXT STEP UP FROM THAT IS AN ALJ PROCEEDING, AND THEN THERE IS
10:25AM 3 FEDERAL COURT REVIEW AND POTENTIAL APPEAL RIGHTS AND THE LIKE.

10:25AM 4 AND I ACTUALLY THINK IT'S HELPFUL TO -- I THINK THAT THE
10:26AM 5 STRUCTURE OF THE CMS REPORT KIND OF DRILLS THIS POINT HOME.

10:26AM 6 MS. SAHARIA, IF YOU COULD PULL UP THE REPORT? THIS IS
10:26AM 7 DEFENSE EXHIBIT 12 AT ECF 581-1.

10:26AM 8 THIS IS WHERE WE HAVE THE JANUARY 2016 REPORT.

10:26AM 9 SO IT BEGINS WITH A COVER LETTER THAT IS NOTIFYING THE
10:26AM 10 COMPANY THAT THERE HAVE BEEN CERTAIN CONDITION AND STANDARD
10:26AM 11 LEVEL DEFICIENCIES IDENTIFIED AND THAT THERE'S BEEN AN
10:26AM 12 IMMEDIATE JEOPARDY FINDING, AND IT CITES THE REGULATORY
10:26AM 13 PROVISIONS THAT ARE IN -- THAT ARE GOING TO BE CITED LATER ON.

10:27AM 14 IT INFORMS THE LABORATORY OF ITS RULINGS AND IT REQUESTS A
10:27AM 15 RESPONSE WITHIN 10 DAYS, WHICH IS A PRETTY AGGRESSIVE
10:27AM 16 TIMEFRAME.

10:27AM 17 IF YOU LOOK AT ONE EXAMPLE OF THE CITATION -- SO WE CAN GO
10:27AM 18 TO THE FIRST DEFICIENCY -- YOU KNOW, NO PARTICULAR DEFICIENCY
10:27AM 19 IS UNIQUE. THEY ALL FOLLOW THE SAME STRUCTURE.

10:27AM 20 THEY START OUT WITH FIRST THE REGULATORY TEXT. EACH ONE
10:27AM 21 OF THEM, THEY COPY AND PASTE THE WHOLE REGULATION IN, AND THEN
10:27AM 22 IT SETS FORTH WHAT FEELS LIKE AN ADJUDICATION AND NOT A ROUTINE
10:27AM 23 MINISTERIAL OBSERVATION. IT IS, I REVIEWED FACTS AND I'M
10:27AM 24 OPINING THESE FACTS AS TO THE LAW AND I'M FINDING EITHER THE
10:27AM 25 CONDITION LEVEL OR STANDARD LEVEL REGULATORY REQUIREMENT NOT

10:27AM 1 MET.

10:27AM 2 IT THEN SUMMARIZES THE FACTS IN ITS DETERMINATION AND IT
10:27AM 3 USES THE PHRASE "BASED ON." SO EACH ONE OF THESE ARE KIND OF
10:27AM 4 LIKE A MINI LITTLE RULING FROM A GOVERNMENT AGENT WHO WENT INTO
10:27AM 5 A LABORATORY AND KIND OF HAD FREE REIN TO PICK AROUND, AND I
10:28AM 6 THINK THIS REPORT REALLY ANSWERS THE QUESTION OF, IF THIS IS
10:28AM 7 SOMETHING THAT THEY HAD AN OBLIGATION TO REPORT, IS THIS
10:28AM 8 SOMETHING THAT CAME ACROSS SARAH BENNETT'S DESK ONE DAY AND
10:28AM 9 THAT SHE STAMPED?

10:28AM 10 NO. THIS IS A GOVERNMENT INVESTIGATION. THAT'S REALLY
10:28AM 11 WHY IT'S (A) (3), (A) (3). THAT'S REALLY WHY WE SHOULD ONLY BE
10:28AM 12 DEALING WITH THAT.

10:28AM 13 BUT ASSUMING THAT WE'RE IN (A) (2), THAT'S WHY CMS WAS
10:28AM 14 ACTING AS LAW ENFORCEMENT IN ITS CAPACITY. IT'S AN ADVERSARIAL
10:28AM 15 INTERACTION, AND ADVERSARIAL DOESN'T MEAN IT HAS TO BE NASTY,
10:28AM 16 IT'S JUST, WE ARE INSPECTING YOU AND YOU HAVE TO OPEN YOUR
10:28AM 17 BOOKS AND WE ARE GOING TO LOOK AT THEM ALL AND THERE IS
10:28AM 18 POTENTIAL CIVIL AND, IMPORTANTLY, CRIMINAL LIABILITY FOR WHAT
10:28AM 19 WE FIND, AND WE'RE GOING TO TAKE THIS AND WE'RE GOING TO TELL
10:28AM 20 YOU WHAT WE FOUND AND THAT'S GOING TO KICK OFF A SERIES OF
10:29AM 21 STEPS THAT COULD VERY LIKELY LEAD TO LITIGATION.

10:29AM 22 SO I DON'T THINK THAT THIS IS JUST AN OBSERVATION,
10:29AM 23 SOMETHING THAT WAS OBSERVED UNDER A DUTY TO REPORT.

10:29AM 24 THE COURT: ISN'T THAT THEIR CHARGE, THEY'RE
10:29AM 25 SUPPOSED TO GO OUT AND LOOK AT LABORATORIES AND THEY HAVE THEIR

10:29AM 1 CLIPBOARDS AND THEIR CHECKLISTS AND THEY PICK THINGS OFF?

10:29AM 2 MR. LOOBY: THERE ARE NO CHECKLISTS. THERE ARE A
10:29AM 3 FEW MANUALS THAT KIND OF EXPLAIN WHAT THEY SHOULD BE LOOKING
10:29AM 4 ATM AND THEY USE THE PHRASE KIND OF OUTCOME DETERMINATIVE.

10:29AM 5 BUT THE THRUST OF ALL OF THE GUIDANCE MATERIAL THAT CMS
10:29AM 6 PUTS UP IS THAT IT REALLY RESTS A LOT OF THE DECISION MAKING IN
10:29AM 7 THE DISCRETION OF ITS INSPECTORS.

10:29AM 8 THEY ARE GIVEN, YOU KNOW, FULL DISCRETION OVER KIND OF
10:29AM 9 WHAT YOU SHOULD ASK ABOUT, WHAT LEVEL OF DOCUMENTATION SHOULD
10:29AM 10 MAKE THEM COMFORTABLE THAT THE LAB IS EITHER COMPLIANT, OR HOW
10:29AM 11 MUCH THEY NEED TO SEE TO DETERMINE IF THEY'RE NOT COMPLIANT.

10:29AM 12 IF THEY'RE NOT COMPLIANT, IS IT STANDARD LEVEL? IS IT
10:30AM 13 CONDITION LEVEL? IS THERE IMMEDIATE JEOPARDY?

10:30AM 14 YOU KNOW, THERE ARE NO RULES ABOUT THIS. AND THIS IS WHAT
10:30AM 15 SARAH BENNETT TOLD THE GOVERNMENT, AND SHE ALSO TOLD THEM THIS,
10:30AM 16 YOU KNOW, OF COURSE THERE ARE CERTAIN THINGS THAT A LAB
10:30AM 17 INSPECTOR PROBABLY HAS A -- THIS IS WHAT I DO. I'VE BEEN ON
10:30AM 18 THE JOB FOR 20 YEARS. I'M GOING TO LOOK AT THE QC DATA, I'M
10:30AM 19 GOING TO LOOK AT THE PC DATA. BUT THAT -- JUST BECAUSE THOSE
10:30AM 20 ARE A LITTLE BIT ROUTINE DOESN'T MEAN THE OBSERVATIONS THEY'RE
10:30AM 21 MAKING ARE NOT REQUIRING DISCRETION, PROFESSION JUDGMENT, AND
10:30AM 22 DISCERNMENT.

10:30AM 23 I SHOULD ALSO ADD, AS I MENTIONED EARLIER, THE REPORT AT
10:30AM 24 MANY JUNCTURES WILL KIND OF SAY WHAT THE CLIA LAB STAFF AT
10:30AM 25 THERANOS TOLD THE INSPECTOR. SO IT WILL SAY, LIKE, I FOUND

10:30AM 1 THERE WASN'T PAPERWORK FOR THIS. I ASKED THE QA MANAGER WHERE
10:31AM 2 IS IT AND HE SAID HE COULDN'T FIND IT.

10:31AM 3 SOME OF THESE FINDINGS, AND WE DON'T HAVE TO GET INTO IT,
10:31AM 4 BUT SOME OF THESE OBSERVATIONS IN THE JANUARY REPORT, THEY'RE
10:31AM 5 VERY MUCH CONTESTED IN THE CASE AND THERE'S EVIDENCE -- THERE'S
10:31AM 6 GOING TO BE EVIDENCE IN THE CASE THAT SUGGESTS THAT MAYBE
10:31AM 7 THEY'RE AN INCOMPLETE PICTURE, AND THAT REALLY IS -- KIND OF
10:31AM 8 DRIVES HOME THE DANGER OF PUTTING IN KIND OF THE JANUARY 2016
10:31AM 9 REPORT THAT INCLUDES MULTIPLE -- THE WHOLE THING IS HEARSAY,
10:31AM 10 BUT WITHIN IT THERE'S ALSO HEARSAY. AND IT HASN'T BEEN TESTED.

10:31AM 11 THERANOS EVENTUALLY KIND OF SETTLED THE MATTER WITH CMS.
10:31AM 12 IT DOESN'T BEHOOVE A LAB COMPANY TO KIND OF GO THROUGH EACH
10:31AM 13 CITATION NECESSARILY AND OFFER -- KIND OF FIGHT WITH THE
10:31AM 14 AGENCY. A LOT OF THERANOS'S RESPONSES WERE, WE ARE WORKING TO
10:31AM 15 BE BETTER.

10:31AM 16 THE COURT: OKAY. ALL RIGHT.

10:31AM 17 MR. LOOBY: THANK YOU, YOUR HONOR.

10:31AM 18 THE COURT: MR. LEACH, ARE YOU RISING TO RESPOND TO
10:32AM 19 THIS?

10:32AM 20 MR. LEACH: I AM.

10:32AM 21 THE COURT: WELL, I'M EAGER TO HEAR YOUR RESPONSE,
10:32AM 22 BUT LET'S TAKE A BREAK. WE'LL TAKE ABOUT 10 OR 15 MINUTES NOW.
10:32AM 23 ALL RIGHT.

10:32AM 24 MR. LEACH: OF COURSE.

10:32AM 25 THE COURT: THANK YOU.

10:32AM 1 THE CLERK: THE COURT WILL TAKE A RECESS AT THIS
10:32AM 2 POINT.

10:33AM 3 (RECESS FROM 10:33 A.M. UNTIL 10:51 A.M.)

10:51AM 4 THE COURT: WE'RE BACK ON THE RECORD. ALL PARTIES
10:51AM 5 PREVIOUSLY PRESENT ARE PRESENT ONCE AGAIN.

10:51AM 6 MR. LEACH, YOU'D LIKE TO RISE FOR THE GOVERNMENT AS TO
10:51AM 7 THIS MOTION?

10:51AM 8 MR. LEACH: YES. THANK YOU VERY MUCH, YOUR HONOR.

10:52AM 9 SO THE OBJECTIONS TO THE CMS SURVEY FINDINGS ARE
10:52AM 10 THREE-FOLD: RELEVANCE, 403, AND HEARSAY, AND I'D LIKE TO TAKE
10:52AM 11 THEM IN THAT ORDER IF I COULD, YOUR HONOR.

10:52AM 12 RELEVANCE, OBVIOUSLY, IS A LOW STANDARD. WE SET THAT
10:52AM 13 FORTH IN THE BRIEF. AND JUST TO GIVE YOU SOME CONCRETE
10:52AM 14 EXAMPLES, IF A CMS INSPECTOR GOES INTO THERANOS LAB AND SEES
10:52AM 15 THAT AN EDISON DEVICE IS FAILING QC FOR 15 CONSECUTIVE DAYS,
10:52AM 16 THAT TENDS TO SHOW THERE ARE ISSUES WITH THE EDISON, WHICH GOES
10:52AM 17 DIRECTLY TO THE INVESTOR COUNT AND DIRECTLY TO THE PATIENT
10:52AM 18 COUNT.

10:52AM 19 IF A CMS INSPECTOR GOES INTO THE THERANOS LAB AND SEES
10:52AM 20 THAT A SET OF DOCUMENTS SHE'S ASKED FOR AND IS REVIEWING A
10:52AM 21 THERANOS EDISON DEVICE HAS FAILED QC, BUT THEY'RE STILL
10:53AM 22 REPORTING PATIENT RESULTS, THAT'S OBVIOUSLY EVIDENCE THAT THE
10:53AM 23 DEVICE ISN'T WORKING AND THAT THERANOS IS IGNORING RED FLAGS
10:53AM 24 ABOUT ITS DEVICE.

10:53AM 25 I HEARD MY FRIEND ON THE FRIEND ON THE OTHER SIDE THAT THE

10:53AM 1 QC IS AN INDICATOR THAT SOMETHING IS AWRY. I COULDN'T AGREE
10:53AM 2 MORE WITH THAT.

10:53AM 3 AND LABS LIKE THERANOS ARE SUPPOSED TO HAVE QC PROCEDURES
10:53AM 4 TO IDENTIFY WHAT THE PROBLEM IS, INVESTIGATE IT, AND FIX IT.

10:53AM 5 THAT'S NOT A PROCEDURE CMS IS CHECKING TO MAKE SURE THAT
10:53AM 6 THEY'RE FOLLOWING THEIR OWN PROCEDURES. CMS HAS STANDARDS AND
10:53AM 7 CONDITIONS AND IT'S MAKING SURE THOSE STANDARDS AND CONDITIONS
10:53AM 8 ARE BEING FOLLOWED. SO IT'S MUCH MORE THAN JUST A FAILURE TO
10:53AM 9 FOLLOW PROCEDURE THERE.

10:53AM 10 AND THESE ARE NOT JUST MY RELEVANCE ARGUMENTS, YOUR HONOR.
10:53AM 11 THESE ARE RELEVANCE ARGUMENTS THAT THE DEFENDANT MADE IN
10:53AM 12 REALTIME TO HER BOARD AND ON HER WEBSITE.

10:53AM 13 SHE SAYS ONE OF THE WAYS YOU KNOW THAT THERANOS'S TESTS
10:53AM 14 ARE ACCURATE AND RELIABLE IS BECAUSE OF ITS CLIA ACCREDITATION,
10:54AM 15 BECAUSE IT'S COMPLYING WITH THESE STANDARDS AND CONDITIONS.
10:54AM 16 SHE DREW THE RELEVANCE CONNECTION.

10:54AM 17 ALTHOUGH I THINK IT'S PATENT FROM A CMS INSPECTOR GOING IN
10:54AM 18 AND LOOKING AT THE EDISONS AND LOOKING AT THE DOCUMENTS THAT
10:54AM 19 ARE PROVIDED.

10:54AM 20 IN ADDITION, I THINK THEY ARE CHERRY PICKING CERTAIN
10:54AM 21 STATEMENTS FROM SARAH BENNETT, THE CMS INSPECTOR WHO WE EXPECT
10:54AM 22 TO TESTIFY TO SAY THAT CMS REGULATIONS HAVE NOTHING TO DO WITH
10:54AM 23 ACCURACY AND RELIABILITY. SHE WILL NOT SAY THAT.

10:54AM 24 THESE STANDARDS AND CONDITIONS ARE DESIGNED TO ENSURE
10:54AM 25 ACCURACY AND RELIABILITY. THEY DON'T, YOU KNOW, EXIST FOR

10:54AM 1 THEIR OWN SAKE IN A VACUUM. THEY'RE THERE AS THE MEASURES TO
10:54AM 2 MAKE SURE THAT THESE TESTS ARE ACCURATE AND RELIABLE.

10:54AM 3 AND WHAT THE GOVERNMENT IS SEEKING FROM THE CMS FINDINGS
10:54AM 4 IS THE OBSERVATIONS THAT THESE INSPECTORS MAKE WHEN THEY GO IN
10:54AM 5 IN SEPTEMBER OF 2015. WHAT WAS THE QC DATA FOR THIS EDISON
10:55AM 6 DEVICE ON THESE DATES? WHAT DID YOU SEE IN TERMS OF CV'S AND
10:55AM 7 STANDARD VARIATIONS FOR THESE ASSAYS? WHAT DID YOU SEE THAT
10:55AM 8 THERANOS HAD DONE ABOUT IT WHEN THEY WERE OUT OF RANGE? AND
10:55AM 9 THE ANSWER, FOR THE MOST PART, IS NOTHING.

10:55AM 10 AND THESE THINGS THAT CMS SEES, HEARS, AND DOES, IT'S WHAT
10:55AM 11 THEY DO EVERY DAY IN THEIR INSPECTIONS, AND THEY WILL BE
10:55AM 12 SUBJECT TO CROSS-EXAMINATION. I JUST -- I DON'T THINK THERE'S
10:55AM 13 A CLOSE QUESTION ON RELEVANCE AND 403.

10:55AM 14 THESE OBVIOUSLY GO TO THE HEART OF THE GOVERNMENT'S
10:55AM 15 ALLEGATIONS. I THINK SARAH BENNETT AND THE CMS STANDARDS DRAW
10:55AM 16 THE CONNECTION BETWEEN ACCURACY AND RELIABILITY, AND THIS
10:55AM 17 REALLY IS A CASE OF ONE OF THE ONLY TIMES WHERE SOMEBODY FROM
10:55AM 18 THE OUTSIDE GOT A LOOK UNDER THE HOOD AT THERANOS AND REPORTED
10:55AM 19 WHAT THEY SAW.

10:55AM 20 AND WHAT THEY SAW WAS SO TROUBLING THAT THEY ISSUED THE
10:55AM 21 FORM 2567 WHICH FOUND THAT THERE WAS IMMEDIATE JEOPARDY TO
10:56AM 22 PATIENTS BECAUSE CERTAIN STANDARDS AND CONDITIONS WEREN'T BEING
10:56AM 23 MET.

10:56AM 24 THE COURT: CAN I ASK YOU SOMETHING? I'M SORRY TO
10:56AM 25 INTERRUPT YOUR PRESENTATION.

10:56AM 1 BUT ON A 403 QUESTION, WOULD THAT -- IS THAT MORE
10:56AM 2 PREJUDICIAL THAN PROBATIVE? IF THE STATEMENT COMES IN, IF THIS
10:56AM 3 COMES IN, I THINK YOUR COLLEAGUE OPPOSITE WOULD SAY, WELL, EVEN
10:56AM 4 IF IT COMES IN, JUDGE, YOU CAN'T LET THAT IN BECAUSE THAT'S FAR
10:56AM 5 TOO PREJUDICIAL AND THE PROBATIVE VALUE IS CLEARLY OUTWEIGHED
10:56AM 6 BY THE PREJUDICIAL IMPACT THAT IT WOULD HAVE ON A JURY,
10:56AM 7 INDICATING RED LIGHTS FLASHING.

10:56AM 8 MR. LEACH: I DIDN'T HEAR THAT SPECIFIC ARGUMENT
10:56AM 9 FROM MY COLLEAGUE, AND CERTAINLY WE ARE OPEN TO REDACTIONS TO
10:56AM 10 THE REPORT, OR IF THERE ARE SPECIFIC ASPECTS LIKE THAT THAT ARE
10:56AM 11 IN THE 403 BALANCING, I CERTAINLY THINK THAT IS IN PLAY
10:57AM 12 SOMEWHERE.

10:57AM 13 BUT I'M A LITTLE HESITANT BECAUSE IT ALSO HAS VERY
10:57AM 14 SPECIFIC LEGAL CONSEQUENCES THAT ARE GOING TO BLEED INTO THE
10:57AM 15 NEXT MOTION, AND I WOULDN'T -- YOU KNOW, I CAN FORESEE
10:57AM 16 INSTANCES WHERE MY FRIENDS ON THE OTHER SIDE WANT TO MINIMIZE
10:57AM 17 THE SERIOUSNESS OF SOME OF THE THINGS THAT CMS IS FINDING AND I
10:57AM 18 WOULD WANT TO BE ABLE TO RESPOND TO THOSE.

10:57AM 19 AND ALSO ON JUST THE LEGAL CONSEQUENCES, THE DEFENDANT IS
10:57AM 20 TRYING TO RUN AWAY FROM HER ADMISSIONS AFTER THE CMS REPORT.
10:57AM 21 AFTER THIS DAMAGING REPORT, THEY TOLD CMS -- AND THIS IS AT
10:57AM 22 72-7, I'M SORRY, 727-1 -- "WE, THERANOS, SEE A GLOBAL AND
10:57AM 23 LONG-TERM FAILURE OF QUALITY CONTROL PROGRAM FOR OUR
10:57AM 24 PROPRIETARY DEVICES AND WE CONCLUDE THERE'S A POSSIBLE PATIENT
10:57AM 25 IMPACT FOR EVERY TEST REPORTED ON THE TSPU."

10:58AM 1 THAT'S THERANOS'S WORDS TO CMS THAT THEY'RE TRYING TO RUN
10:58AM 2 AWAY FROM NOW.

10:58AM 3 SO IN THIS 403 BALANCING ON, IS THERE IMMEDIATE JEOPARDY,
10:58AM 4 I DON'T WANT TO CREATE A FALSE IMPRESSION THAT THERE'S NOT
10:58AM 5 SOMETHING VERY, VERY SERIOUS HERE, AND I THINK IT'S ABSOLUTELY
10:58AM 6 CRITICAL THAT THEY ADMIT THAT THERE'S A POSSIBLE IMPACT TO
10:58AM 7 PATIENT TEST RESULTS IN THEIR RESPONSE TO CMS.

10:58AM 8 BUT CERTAINLY THAT TYPE OF -- YOU KNOW, THE CMS REPORT IS
10:58AM 9 A COMBINATION OF FACTUAL OBSERVATIONS THAT THE INSPECTOR IS
10:58AM 10 MAKING, A DETERMINATION OF IS THIS CONDITION BEING MET OR NOT
10:58AM 11 MET, AND SOLICITING A RESPONSE.

10:58AM 12 AND RESPONSE IS IMPORTANT, TOO, BECAUSE MOST OF THERANOS'S
10:58AM 13 RESPONSE IS, YOU'RE RIGHT, YOU'RE RIGHT, WE'LL FIX THAT, YOU'RE
10:58AM 14 RIGHT.

10:58AM 15 NOT THAT DIDN'T HAPPEN.

10:58AM 16 AND THOSE ARE ADMISSIONS.

10:58AM 17 THE COURT: DOES IT MATTER THAT IT NEVER WAS FIXED?

10:59AM 18 MR. LEACH: YES.

10:59AM 19 THE COURT: AND ULTIMATELY, I THINK THAT'S WHAT THE
10:59AM 20 EVIDENCE WILL SHOW, THAT WHAT I'VE GLEANED HERE, THAT THERE
10:59AM 21 WASN'T COMPLIANCE SUCH THAT THERE WAS SOME TYPE OF A -- IT WENT
10:59AM 22 THROUGH A PROCEDURE AND ULTIMATELY THERE WAS A SETTLEMENT OF
10:59AM 23 SOME SORT.

10:59AM 24 MR. LEACH: WELL, BEFORE THE SETTLEMENT, YOUR HONOR,
10:59AM 25 THERANOS ON ITS OWN ELECTS TO CLOSE, SHUTTER ITS CLIA LAB, AND

10:59AM 1 THAT IS NOT A SETTLEMENT. IT'S A BUSINESS DECISION. I HATE TO
10:59AM 2 USE THE WORD BUSINESS DECISION. IT'S A DECISION THAT
10:59AM 3 MS. HOLMES MADE IN AUGUST OF 2016 TO COMPLETELY SHUTTER THE
10:59AM 4 LAB.

10:59AM 5 SHE TOLD THE PRESS, I KNOW WHAT WE'VE BUILT, AND SHE
10:59AM 6 ESSENTIALLY SAYS, I WANT TO START FROM THE GROUND UP.

10:59AM 7 SO IT DOES END WITH THE LAB BEING SHUTTERED AND THERE IS A
10:59AM 8 FORMAL SETTLEMENT YEARS LATER, BUT IT'S NOT THE SETTLEMENT BY
10:59AM 9 ITSELF THAT RESULTED IN THE LAB BEING CLOSED.

10:59AM 10 THE COURT: THANK YOU. SORRY TO INTERRUPT YOU.

11:00AM 11 MR. LEACH: WITH RESPECT TO THE CONNECTION TO THE
11:00AM 12 RELEVANCE AND 403 ARGUMENTS, THERE ARE LOTS OF FACTUAL
11:00AM 13 OBSERVATIONS IN THE CMS REPORT. WHAT IS THE CD? WHAT DO THE
11:00AM 14 LEVEY-JENNINGS CHARTS SHOW?

11:00AM 15 AND THOSE ARE THE TYPE OF ROUTINE OBSERVATIONS POLICE
11:00AM 16 OFFICERS WOULD BE ABLE TO MAKE IF THEY CAME IN, ALTHOUGH I'M
11:00AM 17 GOING TO GET TO THE LAW ENFORCEMENT THING, AND THEY SHOULD BE
11:00AM 18 ABLE TO TESTIFY TO WHAT THEY SAW, HEARD, DID, AND CONCLUDED
11:00AM 19 DURING THAT EXAM. THAT'S WHAT THEY DO EVERY DAY AND THEY'LL BE
11:00AM 20 SUBJECT TO CROSS-EXAMINATION.

11:00AM 21 SO I JUST DON'T THINK THAT THERE ARE, WITH THE POSSIBLE
11:00AM 22 EXCEPTION THAT YOUR HONOR IS IDENTIFYING, THERE WOULD BE
11:00AM 23 POSSIBLE RELEVANCE OR A 403 ISSUE.

11:00AM 24 WITH RESPECT TO HEARSAY, I REALLY THINK THE UPSHOT OF THE
11:01AM 25 DEFENSE ARGUMENT, YOUR HONOR, IS THAT THERE CAN'T BE GOVERNMENT

1 BUSINESS RECORDS. THEY'RE READING AWAY ON SOME LEVEL 803(8)
2 PARALLELS TO 803(6), AND IT'S BUSINESS RECORDS FOR THE
3 GOVERNMENT.

4 THERE'S A CONFRONTATION CLAUSE ISSUE BREWING HERE. WE
5 CAN'T JUST HAVE THE GOVERNMENT MARKING FBI 302'S AND RESTING
6 OUR CASE. WE JUST CAN'T BE MARKING INS REPORTS FROM 20 YEARS
7 AGO WITHOUT THE ABILITY TO ASK QUESTIONS ABOUT WHAT HAPPENED.

8 THAT'S NOT GOING TO HAPPEN HERE. SARAH BENNETT IS GOING
9 TO BE ON THE STAND AND CAN TESTIFY TO ALL OF THAT.

10 AND THEY WANT TO READ AWAY THIS WORD "OR." WE CAN USE
11 803(8) TO GET IN WHAT LOOKS TO ME A LOT LIKE A GOVERNMENT
12 BUSINESS RECORD.

13 YES, THERE ARE SOME JUDGMENT AND SUBJECTIVITY IN THERE,
14 BUT IF YOU LOOK AT 803(6), IT TOLERATES OPINIONS FROM DOCTORS,
15 IT TOLERATES JUDGMENTS AND CONCLUSIONS, AND THE GOVERNMENT
16 SHOULD NOT GET ANY LESSER OF A BENEFIT HERE, PARTICULARLY WHEN
17 THE WITNESS IS GOING TO BE ON THE STAND ANSWERING QUESTIONS AND
18 CROSS-EXAMINED.

19 THERE'S A LOT OF CONVERSATION ABOUT THE LAW ENFORCEMENT
20 EXCEPTION. THE NINTH CIRCUIT DOES SAY THAT YOU HAVE TO LOOK AT
21 THAT NARROWLY.

22 AND I THINK IT'S A MISTAKE TO TRY TO CATEGORIZE CMS
23 INSPECTORS AS LAW ENFORCEMENT PERSONNEL. THESE ARE LARGELY
24 SCIENTISTS, DOCTORS. THEY DON'T HAVE A GUN. SARAH BENNETT
25 DOES NOT HAVE THE AUTHORITY TO PUT SOMEBODY IN PRISON. SHE'S

11:02AM 1 THERE TO MAKE SURE THAT THE LAB IS MEETING CLIA REGULATIONS
11:02AM 2 WHICH ARE DESIGNED TO ENSURE ACCURACY AND RELIABILITY.

11:02AM 3 AND IF SARAH BENNETT IS LAW ENFORCEMENT PERSONNEL, THEN A
11:02AM 4 WHOLE HOST OF GOVERNMENTAL AGENTS ARE ALSO LAW ENFORCEMENT
11:03AM 5 PERSONNEL, AND YOU'RE ESSENTIALLY WEEDING OUT ANY ABILITY FOR
11:03AM 6 THE GOVERNMENT TO GET WHAT ARE ESSENTIALLY GOVERNMENT BUSINESS
11:03AM 7 RECORDS INTO EVIDENCE.

11:03AM 8 THE COURT: I THINK WHAT MR. LOOBY'S POINT IS, AND
11:03AM 9 HE'LL REMIND US, THAT THE INSPECTORS DO HAVE SOME AUTHORITY,
11:03AM 10 THEY CAN SHUT A LAB DOWN. HE SAID THAT THEY COULD IMPOSE OR
11:03AM 11 PERHAPS RECOMMEND CIVIL FINES, CIVIL PENALTIES.

11:03AM 12 BUT HE SEEMED TO SAY THAT THEY ALSO HAVE SOME AUTHORITY TO
11:03AM 13 EITHER RECOMMEND OR IMPOSE, I CAN'T REMEMBER WHICH HE SAID,
11:03AM 14 CRIMINAL SANCTIONS.

11:03AM 15 MR. LEACH: I THINK THAT'S PROBABLY EQUALLY TRUE FOR
11:03AM 16 A HOST OF CIVIL AUTHORITIES WITHIN HHS, WITHIN OTHER GOVERNMENT
11:03AM 17 AGENCIES, THE S.E.C., FOR EXAMPLE. OBVIOUSLY THEY CAN MAKE
11:03AM 18 RECOMMENDATIONS. THEY CAN REFER SOMETHING.

11:03AM 19 I IMAGINE THAT WAS EQUALLY TRUE IN THE SEVENTH CIRCUIT
11:03AM 20 CASE WITH THE BUILDING INSPECTORS.

11:03AM 21 I THINK THE LINE THAT THE GOVERNMENT IS ADVOCATING HERE
11:04AM 22 FOR IS THAT THERE'S AN INSPECTION ABILITY, AND THEN THERE'S THE
11:04AM 23 INVESTIGATIVE FUNCTION WHERE A LAW ENFORCEMENT AGENCY IS
11:04AM 24 COMMENCING AN INVESTIGATION AND IS GOING OUT AND INTERVIEWING
11:04AM 25 FOLKS WITH AN EYE TOWARDS PROVING A CRIME VERSUS AN INSPECTOR

11:04AM 1 WHO IS THERE TO MAKE SURE THAT THE CIVIL LAW IS BEING FOLLOWED.

11:04AM 2 SO I JUST THINK IT OVERPLAYS THE ROLE OF CMS INSPECTORS TO
11:04AM 3 ANALOGIZE THEM TO AN I.R.S. CRIMINAL INVESTIGATOR OR AN FBI
11:04AM 4 AGENT.

11:04AM 5 AND IF YOU ACCEPT THAT BROAD VIEW, THAT THE POSSIBILITY OF
11:04AM 6 A CRIME BEING OUT THERE SOME DAY ANYTIME THE GOVERNMENT GOES
11:04AM 7 AND TALKS TO THEM, YOU'RE GOING TO READ -- YOU'RE GOING TO
11:04AM 8 DISABLE THE GOVERNMENT FROM EVER GETTING ANY OF THEIR DOCUMENTS
11:04AM 9 INTO EVIDENCE, AND AT A MINIMUM THEY SHOULD BE PERMITTED TO
11:04AM 10 COME IN AND TALK ABOUT WHAT THEY SAW, HEARD, DID, AND
11:05AM 11 CONCLUDED.

11:05AM 12 THE BEST NINTH CIRCUIT AUTHORITY IS FRYBERG THAT SAYS YOU
11:05AM 13 SHOULD READ THAT IN LIMITED FASHION. THE NINTH CIRCUIT HAS
11:05AM 14 READ IT TO INCLUDE CRIMINAL LAW ENFORCEMENT OFFICERS IF THEY'RE
11:05AM 15 REALLY STICKING TO SOMETHING VERY MINISTERIAL.

11:05AM 16 I WOULD ALSO NOTE THAT 803(8) DOES NOT USE THIS SUBJECTIVE
11:05AM 17 MINISTERIAL LANGUAGE. THE STANDARD IS, IS THE INDIVIDUAL UNDER
11:05AM 18 A LEGAL DUTY TO RECORD WHAT THEY'RE DOING, AND HERE
11:05AM 19 SARAH BENNETT ALMOST CERTAINLY IS.

11:05AM 20 MAYBE THERE'S SOME JUDGMENT IN WHAT SHE ASKED FOR, BUT
11:05AM 21 WHATEVER SHE ASKED FOR, SHE WRITES IT DOWN AND THAT'S HER DUTY
11:05AM 22 TO DO THAT.

11:05AM 23 THERE WAS SOME CONVERSATION ABOUT HEARSAY WITHIN THE
11:05AM 24 REPORT. THERE'S, WITHIN THE REPORT, SOME STATEMENT OF THERANOS
11:05AM 25 AGENTS. THERE'S NOT A HEARSAY PROBLEM THERE, YOUR HONOR,

11:05AM 1 BECAUSE THESE ARE STATEMENTS OF AGENTS OF MS. HOLMES. THESE
11:05AM 2 ARE PEOPLE WHO ARE HER AGENTS UNDER OTHER DIVISIONS OF 803.

11:06AM 3 WITH THAT, YOUR HONOR, UNLESS THE COURT HAS FURTHER
11:06AM 4 QUESTIONS, I'LL SUBMIT.

11:06AM 5 THE COURT: NO. THANK YOU.

11:06AM 6 MR. LOOBY: SO WITH THE COURT'S INDULGENCE, I THINK
11:06AM 7 WE'LL START WITH HEARSAY BECAUSE THAT'S WHERE WE ENDED.

11:06AM 8 SO THE GOVERNMENT IS RELYING ON THE FRYBERG CASE OUT OF
11:06AM 9 THE NINTH CIRCUIT, AND IN THE -- FRYBERG INVOLVED A RETURN OF
11:06AM 10 SERVICE FORM THAT WAS SERVED BY A TRIBAL POLICE OFFICER. SO
11:06AM 11 THE FACT THAT THE OFFICER WAS LAW ENFORCEMENT WASN'T IN DISPUTE
11:06AM 12 IN THE CASE, BUT THE QUESTION WAS, WELL, IS THE OBSERVATION
11:06AM 13 REFLECTED ON THE RETURN OF SERVICE, THAT SERVICE HAD TAKEN
11:06AM 14 PLACE, WAS IT AN OBJECTIVE ONE, NOT THE TYPE OF SUBJECTIVE
11:07AM 15 OBSERVATION SUMMARY OPINION OR CONCLUSION OF THE LAW
11:07AM 16 ENFORCEMENT PERSONNEL.

11:07AM 17 SO THE NINTH CIRCUIT MIGHT READ LAW ENFORCEMENT NARROWLY
11:07AM 18 AS THEY SAY -- THE LAW ENFORCEMENT EXCEPTION NARROWLY AS THEY
11:07AM 19 SAY IN FRYBERG, BUT WHEN THEY SAY THAT, THEY MEAN THEY'RE
11:07AM 20 ASKING THAT SECOND QUESTION: IS THIS LAW ENFORCEMENT OFFICER,
11:07AM 21 ARE THEY MAKING OBJECTIVE OBSERVATIONS? ARE THEY RECORDING THE
11:07AM 22 LICENSE PLATES? OR ARE THEY MARKING THAT SERVICE WAS INDEED
11:07AM 23 EFFECTUATED ON THIS PERSON TO PROVE THAT HE WAS GIVEN NOTICE,
11:07AM 24 WHICH WAS AN ELEMENT IN THE CASE, OR WERE THEY DOING SOMETHING
11:07AM 25 MORE?

1 AND FOR ALL OF THE REASONS THAT WE DISCUSSED, THE CMS
2 REPORT, IT'S NOT JUST AN EVERY DAY KIND OF RECORDATION. IT'S
3 AN ASSESSMENT OF AN OPEN RECORD THAT THE CMS INSPECTOR HAS
4 DISCRETION TO CHOOSE FROM.

5 THE COURT: BY A LAW ENFORCEMENT OFFICER?

6 MR. LOOBY: RIGHT, RIGHT.

7 THE COURT: YOUR POSITION IS PREDICATED ON THAT
8 PERSON BEING A LAW ENFORCEMENT OFFICER.

9 MR. LOOBY: WELL, I MEAN, YES. YES AND NO, BECAUSE
10 IN RULE -- IN 803(A) (2) CASES, 803(8) (A) (2) CASES, LIKE, FOR
11 EXAMPLE, THE ROSA CASE OUT OF THE SECOND CIRCUIT, WHICH IS A
12 CASE THAT THE GOVERNMENT CITES, AND THAT'S UNITED STATES V.
13 ROSA, AND THAT'S 11 F.3D 315, AND THAT'S A CASE INVOLVING A
14 MEDICAL EXAMINER AUTOPSY REPORT IN A GANG RELATED CASE.

15 SO THE SECOND CIRCUIT SAID MEDICAL EXAMINERS, THEY'RE NOT
16 LAW ENFORCEMENT. BUT THE DISTRICT COURT PROPERLY, REGARDLESS
17 OF THAT, THE DISTRICT COURT PROPERLY REDACTED ALL OF THE
18 OPINIONS, DIAGNOSES, AND CONCLUSIONS FROM THE REPORT BECAUSE IT
19 WAS OFFERED UNDER SUBSECTION 803(8) (A) (2) BECAUSE THE BUSINESS
20 RECORD EXCEPTION FOR GOVERNMENT RECORDS, WHEN OFFERED AGAINST A
21 CRIMINAL DEFENDANT, IS LIMITED TO THOSE TYPES OF OBSERVATIONS.

22 WE'RE NOT READING OUT ANY POWER OF THE GOVERNMENT THAT
23 THEY HAVE. THIS IS THE RESTRICTION THAT THE DRAFTERS OF THE
24 FEDERAL RULE OF EVIDENCE PUT ON.

25 THEY SAY IF IT'S AN INVESTIGATIVE REPORT, WHICH IS THIS

1 UNDER (A) (3), NO GO, IT'S NOT COMING IN AGAINST A CRIMINAL
2 DEFENDANT.

3 IF IT'S NOT THAT AND WE'RE IN 803(A) (2) LAND AND IT'S AN
4 OBSERVATION THAT THEY REPORTED, WELL, IT CAN COME IN IF IT'S
5 LIKE A BUSINESS RECORD, IF IT'S SOMETHING YOU DO EVERY DAY,
6 SOMETHING THAT YOU RECORD, BUT NOT SOMETHING THAT REQUIRES
7 OBSERVATIONS, DIAGNOSES, AND CONCLUSIONS. SO THAT'S THE ROSA
8 CASE.

9 REALLY ALL OF THE GOVERNMENT'S CASES RECOGNIZE THIS KIND
10 OF DISTINCTION. SO THE EDELMANN CASE OUT OF THE EIGHTH CIRCUIT
11 IN 2006, AND THAT'S AT 458 F.3D 791, SO THIS IS A MAIL FRAUD
12 AND MONEY LAUNDERING CASE, AND THE PIECE OF EVIDENCE AT ISSUE
13 IS A MEMO TO FILE BY, LIKE, A PRISON ADMINISTRATOR. IT HELD
14 THE MANAGER WAS NOT LAW ENFORCEMENT, AND THE COURT WENT ON TO
15 SAY THE MEMO DOES NOT CONTAIN ANY OPINIONS, FINDINGS, OR
16 CONCLUSIONS. IT'S A RECORD OF EVENTS COMMUNICATED TO WILSON
17 AND RECORDED CONTEMPORANEOUSLY WITH THE EVENT, WHICH IS
18 SOMETHING THAT SHE OBSERVED IN HER DAILY BUSINESS. IT'S NOT AN
19 INVESTIGATION. IT DOESN'T REQUIRE ANY KIND OF HIGHER LEVEL
20 THINKING.

21 WHEN THOSE TYPES OF DOCUMENTS ARE OFFERED UNDER A HEARSAY
22 EXCEPTION AGAINST A CRIMINAL DEFENDANT, THE FEDERAL RULES OF
23 EVIDENCE RESTRICT IT IN CERTAIN CAPACITIES.

24 THE COURT: LET ME STOP YOU THERE.

25 MR. LEACH, COULD YOU COME FORWARD AND WE'LL DO A LITTLE

11:10AM 1 POINT AND COUNTER-POINT AS TO THIS ISSUE, PLEASE.

11:10AM 2 MR. LEACH: AGAIN, YOUR HONOR, THESE AREN'T
11:10AM 3 DISTINCTIONS THAT ARE IN 803(B) -- OR 803(8) (B) . IT'S A DUTY
11:10AM 4 TO REPORT BY SOMEONE WHO IS NOT A LAW ENFORCEMENT PERSONNEL IN
11:11AM 5 A CRIMINAL CASE.

11:11AM 6 AND THE DEFINITION OF "LAW ENFORCEMENT PERSONNEL" DOESN'T
11:11AM 7 CHANGE BASED ON THE PARTICULAR DOCUMENT. IT'S A CATEGORICAL
11:11AM 8 DESCRIPTION.

11:11AM 9 AND THIS DOCUMENT ISN'T THE TYPE WHERE YOU CAN PUT IT ALL
11:11AM 10 IN ONE CATEGORY OR ALL NOT IN THE CATEGORY.

11:11AM 11 SO LAW ENFORCEMENT PERSONNEL IS DESIGNED TO BE GUIDED BY
11:11AM 12 THE FUNCTIONS OF THAT OFFICER.

11:11AM 13 THERE ARE CASES WHERE SOMEBODY WHO IS A LAW ENFORCEMENT
11:11AM 14 OFFICER, THEY STILL TO TOLERATE IT UNDER 803(B) BECAUSE IT'S IN
11:11AM 15 THAT LIMITED CATEGORY.

11:11AM 16 BUT THESE CASES ARE NOT SAYING THAT IF THE PERSON ISN'T
11:11AM 17 THAT LAW ENFORCEMENT OFFICER, YOU APPLY THAT SAME TYPE OF
11:11AM 18 ANALYSIS.

11:11AM 19 THE TEST IS, ARE THEY UNDER A DUTY TO REPORT THE
11:11AM 20 INFORMATION HERE, AND SARAH BENNETT UNQUESTIONABLY WAS.

11:11AM 21 THE COURT: WELL, MR. LOOBY SUGGESTS THAT BECAUSE
11:11AM 22 THE REPORTING GOES A LITTLE BIT FURTHER, IT CALLS FOR OPINIONS,
11:12AM 23 CONCLUSIONS, OBSERVATIONS, THAT CHANGES THE CHARACTER OF THAT
11:12AM 24 REPORT SUCH THAT IT SHOULDN'T COME IN.

11:12AM 25 MR. LEACH: WELL, A BUILDING EXAMINER WILL GO OUT

11:12AM 1 AND SAY, WHAT ARE THE DIMENSIONS OF THIS HOUSE? WHAT IS THE
11:12AM 2 THICKNESS OF THE CONCRETE? WHAT IS THE STATE OF THE
11:12AM 3 ELECTRICITY? NONE OF THOSE THINGS MAKES THAT PERSON A LAW
11:12AM 4 ENFORCEMENT OFFICER.

11:12AM 5 I CONCEDE THERE ARE INSTANCES WHERE SOMEONE WHO IS A LAW
11:12AM 6 ENFORCEMENT OFFICER IS MAKING OBSERVATIONS LIKE, YOU KNOW, THIS
11:12AM 7 GUY VIOLATED THE LAW, OR I FIND X. BUT THAT'S EXCLUDED NOT
11:12AM 8 BECAUSE OF WHAT HE'S FINDING, IT'S EXCLUDED BECAUSE HE'S A LAW
11:12AM 9 ENFORCEMENT OFFICER.

11:12AM 10 SO I ACCEPT THAT THERE ARE GRADATIONS WITHIN THE CMS
11:12AM 11 REPORT, BUT THE CORE OF IT IS THAT WE LOOKED AT THIS DATA, THIS
11:12AM 12 DATA SAID X, THERE'S NO SUBJECTIVITY TO THAT PIECE OF IT.

11:12AM 13 AND THE ONES THAT ARE, ARE NOT EXCLUDABLE BECAUSE
11:13AM 14 SARAH BENNETT EITHER IS OR SHE IS NOT A LAW ENFORCEMENT
11:13AM 15 OFFICER.

11:13AM 16 THE COURT: ALL RIGHT. THANK YOU.

11:13AM 17 MR. LOOBY: THANK YOU, YOUR HONOR.

11:13AM 18 SO I WOULD JUST SAY THAT THE ROSA CASE THAT I CITED TO YOU
11:13AM 19 AND ALSO THE EDELMANN CASES, THESE ARE GOVERNMENT CASES. THESE
11:13AM 20 ARE 803(8) (A) (2) OR (B), DEPENDING ON WHAT THE DIGITS OF THE
11:13AM 21 FEDERAL RULES YOU'RE LOOKING AT. THOSE ARE SUBSECTION
11:13AM 22 (2) CASES ESSENTIALLY, AND THEY ARE LIKE -- IT'S NOT IN THE
11:13AM 23 LANGUAGE OF THE RULE. THE CASE LAW APPLYING IT DOES ASK, DOES
11:13AM 24 THE MEMO CONTAIN OPINIONS, FINDINGS, AND CONCLUSIONS?

11:13AM 25 AND THEN AN ADDITIONAL CITE, AND THIS IS ANOTHER

11:13AM 1 GOVERNMENT CASE, UNITED STATES V. LOPEZ, 762 F.3D 852, AND
11:13AM 2 THAT'S NINTH CIRCUIT 2014. SO THAT'S AN ILLEGAL ALIEN FOUND IN
11:13AM 3 THE U.S. AFTER DEPORTATION CASE. SO THIS IS ALSO ADDRESSING A
11:13AM 4 LAW ENFORCEMENT QUESTION.

11:13AM 5 THE COURT IS ASKING, DOES THE FORM LEAVE ROOM FOR
11:14AM 6 SUBJECTIVITY? NO. THIS IS LIKE A WARRANT OF DEPORTATION.
11:14AM 7 IT'S LIKE THE HERNANDEZ-ROJAS DOCUMENT.

11:14AM 8 SO I WOULD SAY THAT THIS REQUIREMENT, I'M NOT MAKING IT
11:14AM 9 UP, IT'S IN THE CASE LAW.

11:14AM 10 THE COURT: OKAY. ALL RIGHT. THANK YOU. ANYTHING
11:14AM 11 FURTHER?

11:14AM 12 MR. LOOBY: YEAH, I DID WANT TO ADDRESS -- TURNING
11:14AM 13 TO THE RELEVANCE ISSUES. I WOULD SAY THAT THERE'S REALLY
11:14AM 14 NOTHING INCONSISTENT BETWEEN THE STATEMENTS THAT THE GOVERNMENT
11:14AM 15 RAISES THAT THERANOS MADE PRIOR TO THE INSPECTION SAYING WE ARE
11:14AM 16 CLIA CERTIFIED AND WE TAKE PRIDE IN OUR CLIA CERTIFICATION, AND
11:14AM 17 THE DEFENSE ARGUMENTS TODAY.

11:14AM 18 AND THE ONLY WAY THAT YOU FIND INCONSISTENCY THERE IS IN
11:14AM 19 MISCHARACTERIZING OUR POSITION TO SAY THAT CLIA REGULATIONS AND
11:14AM 20 CMS INSPECTIONS HAVE NOTHING TO DO WITH LAB QUALITY.

11:15AM 21 WE ARE, OF COURSE, NOT SAYING THAT. IT'S A COMPREHENSIVE
11:15AM 22 REGULATORY SCHEME THAT SETS UP WHAT KIND OF PROCEDURES THE
11:15AM 23 DOCUMENTATION THE LAB HAS TO KEEP.

11:15AM 24 THE PURPOSE FOR IT IS, YES, TO PROMOTE HEALTHY AND GOOD
11:15AM 25 LAB PRACTICES AND, YES, LAB PERFORMANCE.

11:15AM 1 BUT THE OPPOSITE IS NOT TRUE FOR ALL OF THE REASONS THAT
11:15AM 2 WE DISCUSSED EARLIER.

11:15AM 3 ANY CLIA REGULATORY CITATION DOESN'T MEAN THAT THE LAB
11:15AM 4 IS -- A, HAS IN THE PAST PRODUCED INACCURATE OR UNRELIABLE
11:15AM 5 RESULTS, OR TYING IT TO THE ACTUAL ALLEGATIONS IN THIS CASE, IS
11:15AM 6 INCAPABLE OF DOING THAT.

11:15AM 7 THAT'S NOT WHAT THE CLIA REGULATIONS AND CITATIONS SAY.
11:15AM 8 SO IT'S THAT -- IT'S THAT GAP BETWEEN THE INHERENT LIMIT OF
11:15AM 9 WHAT THIS EVIDENCE IS AND WHAT THE GOVERNMENT WANTS THE JURY TO
11:15AM 10 DO FOR IT.

11:15AM 11 I HEARD IN MY FRIEND'S ARGUMENT THAT THIS IS JUST PATENT
11:15AM 12 IN THE FORM. THE JURY CAN LOOK AT IT AND SEE, OH, THIS CV
11:16AM 13 PERCENTAGE IS 63 PERCENT ON THIS WEEK IN APRIL 2014. I CAN
11:16AM 14 UNDERSTAND THAT THAT MEANS THAT THERANOS WAS INCAPABLE OF
11:16AM 15 CONSISTENTLY PRODUCING ACCURATE AND RELIABLE RESULTS.

11:16AM 16 AND, RESPECTFULLY, YOUR HONOR, I DON'T KNOW HOW A JURY CAN
11:16AM 17 DO THAT FOR ALL OF THE REASONS WE SET FORTH BECAUSE THERE'S
11:16AM 18 JUST A GAP BETWEEN THE USE OF THIS EVIDENCE AND WHAT IT IS AND
11:16AM 19 ITS INHERENT LIMITATIONS AND THE DISTINCTION THAT THE -- THE
11:16AM 20 INFERENCES THAT THE GOVERNMENT WANTS THE JURY TO DRAW.

11:16AM 21 THE COURT: IS THERE A GAP, MR. LEACH?

11:16AM 22 MR. LEACH: THERE IS NO GAP, YOUR HONOR.

11:16AM 23 AND IF THERE IS, YOU DON'T LOOK AT ONE PIECE OF EVIDENCE
11:16AM 24 IN A VACUUM. THERE ARE OTHER WITNESSES WHO ARE TALKING ABOUT
11:16AM 25 CV'S. THERE'S ERICA CHEUNG, WHO IS GOING TO COME IN AND TALK

11:16AM 1 ABOUT ALL OF THE QUALITY CONTROL PROBLEMS WE HAD AND HOW WE
11:16AM 2 WERE NOT DOING ANYTHING ABOUT IT, AND I COMPLAINED TO CMS AND
11:16AM 3 THAT'S WHY CMS CAME IN.

11:16AM 4 SO THERE'S NO GAP. READING THE REPORT, YOU SEE THAT THIS
11:17AM 5 EDISON DEVICE IS PRODUCING RESULTS FOR VITAMIN D THAT ARE WAY
11:17AM 6 OUT OF WHACK FOR MANY, MANY DAYS. THAT IS A FACT FROM WHICH A
11:17AM 7 JURY CAN DRAW THAT TENDS TO SHOW THE EDISON DEVICE WAS NOT
11:17AM 8 CAPABLE OF DOING WHAT IT SAID IT WAS. THERE IS NO GAP
11:17AM 9 WHATSOEVER.

11:17AM 10 AND EVEN IF THERE WAS, THIS IS NOT THE ONLY PIECE OF
11:17AM 11 EVIDENCE THAT THE GOVERNMENT IS GOING TO PRESENT. YOU HAVE TO
11:17AM 12 LOOK AT THIS AS A RELEVANCE QUESTION LOOKING AT THE WHOLE OF
11:17AM 13 THE GOVERNMENT'S PRESENTATION.

11:17AM 14 MR. LOOBY: WELL, TO BORROW FROM THE ANALOGY I HEARD
11:17AM 15 YESTERDAY OF KIND OF BRICKS IN THE WALL, THIS ISN'T THE TYPE OF
11:17AM 16 EVIDENCE THAT IS BEING PRESENTED TO THE JURY AS A BRICK THAT
11:17AM 17 CAN FIT INTO A WALL THAT WILL SCALE TO A CONCLUSION THE JURY
11:17AM 18 COULD MAKE ABOUT ACCURACY AND RELIABILITY.

11:17AM 19 I DON'T THINK THAT THE JURY CAN SIT THERE AND SAY, OKAY,
11:17AM 20 THESE QC RESULTS ON PAGE 54 OF THIS 100 AND ODD PAGE REPORT, IT
11:17AM 21 LOOKS LIKE THEY WERE OFF FOR THIS WEEK ON THE VITAMIN D, THE
11:18AM 22 MACHINE RUNNING VITAMIN D. THESE AREN'T VITAMIN D RESULTS.
11:18AM 23 THESE ARE QC DATA GENERATED ON DEVICES THAT WERE RUNNING THAT
11:18AM 24 PARTICULAR ASSAY. SO WE'RE ALREADY AT ONE LEVEL REMOVED.

11:18AM 25 AND THEN THEY'RE GOING TO TAKE THAT AND THEY ARE GOING TO

1 SAY THAT NUMBER SOUNDS REALLY BAD. HERE IS SOME OTHER EVIDENCE
2 IN THE CASE WHERE SOMEBODY IS TALKING ABOUT QC, AND I'M GOING
3 TO PUT THEM TOGETHER AND I'M GOING TO SAY NOW I UNDERSTAND IN
4 CONTEXT WHAT THIS MEANS.

5 THAT'S NOT SOMETHING THAT THE JURY IS GOING TO BE ABLE TO
6 DO. AND THIS REALLY GOES BOTH TO THE ACCURACY -- THE RELEVANCY
7 ISSUE BUT REALLY THE 403 ISSUE AS WELL WHICH IS THAT THIS GIANT
8 REPORT IS GOING TO BE DUMPED IN FRONT OF THE JURY, AND THEY'RE
9 NOT REALLY GOING TO KNOW WHAT THIS IS.

10 THE COURT: THAT'S A GOOD QUESTION. I WANTED TO --
11 ARE YOU ASKING THAT THE ENTIRETY OF THE REPORT COME IN?
12 PORTIONS OF IT? OR YET TO BE DETERMINED?

13 MR. LEACH: WE THINK THE ENTIRE REPORT SHOULD COME
14 IN FOR ITS CONTEXT, BUT CERTAINLY I'M HAPPY TO WORK WITH THE
15 OTHER SIDE FOR REDACTIONS. BUT I THINK THE ENTIRE REPORT FOR
16 ITS CONTEXT IS RELEVANT.

17 OBVIOUSLY, I'M NOT GOING TO ASK THE JURY TO PLOW THROUGH
18 EVERY SINGLE PAGE, BUT IT WILL BE INCUMBENT ON THE GOVERNMENT
19 TO ISOLATE THE PARTICULAR OBSERVATIONS, AND WE'VE DONE SOME OF
20 THAT WORK IN THIS BRIEF, BUT I WOULDN'T WANT THINGS TO BE TAKEN
21 OUT OF CONTEXT. BUT IT IS -- WE ARE SEEKING THE ENTIRETY OF
22 THE REPORT.

23 THE COURT: OKAY. ALL RIGHT. GREAT. THANK YOU
24 VERY MUCH.

25 MR. LEACH: THANK YOU.

11:19AM 1 MR. LOOBY: THANK YOU.

11:19AM 2 THE COURT: THIS MOTION IS UNDER SUBMISSION. THE
11:19AM 3 COURT WILL ISSUE AN ORDER, A WRITTEN ORDER.

11:19AM 4 ARE WE AT 572? THIS IS MS. HOLMES'S MOTION TO EXCLUDE
11:20AM 5 EVIDENCE OF REMEDIAL MEASURES AND SETTLEMENTS.

11:20AM 6 MR. FLEURMONT: GOOD AFTERNOON, YOUR HONOR.

11:20AM 7 J.R. FLEURMONT FOR MS. HOLMES.

11:20AM 8 THE COURT: THANK YOU.

11:20AM 9 MR. FLEURMONT: YOUR HONOR, THIS MOTION CONCERNS TWO
11:20AM 10 CATEGORIES OF EVIDENCE. THE FIRST IS ALLEGED EVIDENCE OF
11:20AM 11 THERANOS RUINING A SMALL PERCENTAGE OF ITS TESTS THAT WE
11:20AM 12 BELIEVE SHOULD BE EXCLUDED UNDER RULE 407.

11:20AM 13 IT ALSO CONCERNS EVIDENCE OF SETTLEMENTS WITH CMS AND THE
11:20AM 14 ARIZONA ATTORNEY GENERAL'S OFFICE THAT WE BELIEVE SHOULD BE
11:20AM 15 EXCLUDED UNDER RULE 408.

11:20AM 16 NOW, AS TO THE LATTER CATEGORY, THE GOVERNMENT NOTICED ITS
11:20AM 17 INTENT TO MAKE ARGUMENT ABOUT THOSE SPECIFIC SETTLEMENTS IN
11:20AM 18 OPPOSITION TO OUR MOTION, IT'S THIS CLAIM THAT IT INTENDS. AND
11:20AM 19 SO -- THAT'S AT DOCKET 673 AT PAGE 1, FOOTNOTE 1.

11:20AM 20 SO WE JUST ASK THAT IT BE MEMORIALIZED IN AN ORDER. SO
11:20AM 21 ACCORDINGLY I WILL JUST FOCUS ON THE VOIDING IF THAT'S OKAY
11:21AM 22 WITH YOU.

11:21AM 23 THE COURT: OKAY.

11:21AM 24 MR. FLEURMONT: THE EVIDENCE OF VOIDING SHOULD BE
11:21AM 25 EXCLUDED FOR TWO PRINCIPLE REASONS. THE FIRST IS THAT IT'S

1 BARRED BY 407'S PROHIBITION ON SUBSEQUENT REMEDIAL MEASURES,
2 AND THE SECOND, IT'S BARRED BY RULE 401 AND 403 AS NOT RELEVANT
3 AND UNFAIRLY PREJUDICIAL.

4 SO STARTING WITH RULE 407. UNDER FEDERAL RULE 407
5 EVIDENCE OF SUBSEQUENT REMEDIAL MEASURES ARE EXCLUDED IF
6 THEY'RE OFFERED TO PROVE NEGLIGENCE, CULPABLE CONDUCT, OR A
7 DEFECT IN A PRODUCT OR ITS DESIGN.

8 IN THIS CASE IT'S 404(B) NOTICE, EXHIBIT 1, THE GOVERNMENT
9 HAS STATED ITS INTENT TO INCLUDE SUCH EVIDENCE TO SHOW THAT,
10 AND I QUOTE, "DEFENDANTS INTENDED TO DEFRAUD PATIENTS BY
11 DEPRIVING THEM OF INFORMATION THEY BELIEVED THAT THEY RECEIVED
12 AND PATRONIZING THERANOS'S SERVICES." THAT'S ALL SAID AT
13 EXHIBIT 3 AT PAGES 74 TO 75.

14 NOW, BECAUSE THE GOVERNMENT SEEKS TO USE A SUBSEQUENT
15 REMEDIAL MEASURE TO FILL CULPABILITY, RULE 407 SQUARELY
16 APPLIES.

17 THE GOVERNMENT DOESN'T FIGHT THIS GENERAL PROPOSITION.
18 THEY SEEK TO USE A RULE OF AN EXCEPTION FOR WHEN A REMEDIAL
19 MEASURE IS DONE VOLUNTARILY.

20 THEY CITE IN RE AIRCRAFT THAT IS AT 871 F.2D 812, WHICH
21 STATES THAT THE PURPOSE OF RULE 407 IS NOT IMPLICATED IN CASES
22 INVOLVING SUBSEQUENT REMEDIAL MEASURES AND WHICH A DEFENDANT
23 DID NOT VOLUNTARILY PARTICIPATE.

24 THE PROBLEM IN THIS CASE, ALTHOUGH THERE WERE SEVERAL
25 THINGS THAT WERE REQUIRED BY CMS AND BY CLIA LAWS, VOIDING

11:23AM 1 TESTS WERE NOT ONE OF THEM.

11:23AM 2 MY COLLEAGUE, MR. LOOBY, WALKED YOU THROUGH ALL OF THE
11:23AM 3 PROVISIONS OF CMS AND THE INSPECTION PROCESS AND THAT LEADS TO
11:23AM 4 A SANCTION AND WHAT HAPPENED WITH THAT AND THE APPEAL.

11:23AM 5 IN THIS CASE IT'S CLEAR THAT THERANOS WAS REQUIRED TO
11:23AM 6 ALLOW CMS TO INVESTIGATE AND DO THE INSPECTION, AND THEY WERE
11:23AM 7 REQUIRED TO DO SOME SORT OF CORRECTIVE ACTION WITHIN TEN DAYS.

11:23AM 8 THERE IS NO EVIDENCE IN THIS CASE THAT THERANOS WAS
11:23AM 9 SPECIFICALLY REQUIRED TO VOID ANY OF THESE TESTS, AND IN FACT,
11:23AM 10 THE ONLY EVIDENCE IS TO THE CONTRARY.

11:23AM 11 THE COURT: SO I THINK -- IS YOUR POSITION THAT
11:23AM 12 THERANOS VOLUNTARILY VOIDED THE TESTS, AND THAT'S THE WAY IT
11:23AM 13 SHOULD BE RECEIVED?

11:23AM 14 MR. FLEURMONT: YES, YOUR HONOR, THAT IS OUR
11:23AM 15 POSITION.

11:23AM 16 AS I STATED, THE WAY THAT IT WORKS AND CMS WORKS IS THAT
11:23AM 17 ONCE THEY GIVE YOU THAT INITIAL TERMINATION THAT HAPPENED ON
11:23AM 18 JANUARY 25TH, 2016, THEY HAD TEN DAYS TO REMOVE THE IMMEDIATE
11:23AM 19 JEOPARDY AND PROVIDE A SUBMISSION. THEY PROVIDED THAT
11:24AM 20 SUBMISSION AND THAT WAS REQUIRED.

11:24AM 21 AFTER THAT HAPPENED THERE WAS AN INITIAL IMPOSITION OF
11:24AM 22 SANCTIONS IF CMS CHOOSES TO DO SO, AND THERE'S AN APPELLATE
11:24AM 23 PROCESS THAT LEADS TO A DETERMINATION IN FRONT OF AN ALJ.

11:24AM 24 AFTER THAT INITIAL PROCESS, THAT INSPECTION AND THAT
11:24AM 25 CORRECTIVE ACTION, DECISIONS AFTER THAT ARE VOLUNTARY. IF YOU

1 THINK ABOUT THE PURPOSE OF THE RULE AND WHY YOU HAVE RULE 407,
2 THAT'S TO ENCOURAGE SOMEONE TO DO SOMETHING THAT THEY THINK
3 WOULD BE HELPFUL WITHOUT WORRYING ABOUT LATER LITIGATION AND
4 PENALIZING THEM FOR MAKING THAT HELPFUL KIND OF ACTION.

5 IN THIS CASE I FEEL THAT THE PURPOSE OF THE RULE DOUBLY
6 APPLIES WHEN THERE ARE SOME REQUIREMENTS AND AN ENTITY DECIDED
7 TO DO EVEN MORE THAN WHAT IS REQUIRED PROVIDED BY THE FEDERAL
8 GOVERNMENT, THAT THEY SHOULD NOT BE PENALIZED FOR DOING MORE
9 THAN WHAT IS REQUIRED.

10 THE RULE AS THE CASE IN RE AIRCRAFT STATES IS THAT IF IT'S
11 NOT INVOLUNTARY, THEN YOU DON'T GET THE BENEFIT OF THE RULE.
12 BUT IF YOU GO BEYOND WHAT IS VOLUNTARY -- OR EXCUSE ME. IF YOU
13 GO BEYOND WHAT IS INVOLUNTARY AND YOU WANT TO DO BETTER, AND
14 THAT DOESN'T NECESSARILY MEAN THAT EITHER YOU ARE SAYING THAT
15 THAT IS AN ADMISSION OF GUILT OR THERE IS PROBLEM, BUT YOU JUST
16 REVIEW YOUR PROCESS AND YOU SAY, HEY, MAYBE WE COULD DO A
17 LITTLE BIT BETTER HERE AND LET'S DO IT.

18 BUT A RULE THAT WOULD ALLOW TO USE THAT DECISION IN A
19 SUBSTANTIVE CRIMINAL CASE OR ANY CASE AT ALL FALLS WITHIN THE
20 PURPOSES OF RULE 407.

21 THE COURT: SO WHEN I LOOK AT THIS, AND, AGAIN, I
22 MAY BE LOOKING AT IT WITH A BLURRED LENS PERHAPS, BUT WHEN I
23 SEE "VOLUNTARY," THAT'S, OH, OKAY, WE'RE GOING TO CHANGE THIS.
24 LET'S GET A MEETING TOGETHER OF ADMINISTRATION, WHOEVER THE
25 DECISION MAKERS ARE, AND WE'RE GOING TO CHANGE IT AND, WE'RE

11:26AM 1 GOING TO DO SOMETHING DIFFERENT BECAUSE INTERNALLY IT'S COME TO
11:26AM 2 OUR ATTENTION THAT WE SHOULD.

11:26AM 3 IS THERE A DISTINCTION BETWEEN THAT CORPORATE BUSINESS
11:26AM 4 DECISION AND ONE WHERE WE'VE BEEN CONTACTED BY A REGULATORY
11:26AM 5 OFFICE, AND WE'VE BEEN TALKING WITH THEM FOR WEEKS, MONTHS, AND
11:26AM 6 WE SEE THERE'S A PROBLEM, WE'RE GOING BACK AND FORTH WITH THEM,
11:26AM 7 AND THEY HAVE RATCHETED THIS UP SUCH THAT WE'RE GOING TO BE
11:26AM 8 PENALIZED IF WE DON'T DO SOMETHING. LET'S KEEP TRYING TO FIX
11:26AM 9 THE PROBLEM. OKAY. YOU KNOW WHAT, LET'S TAKE THIS ACTION.

11:26AM 10 IS THAT VOLUNTARY OR IS THAT UNDER THE SHADOW, NOT A
11:26AM 11 THREAT PERHAPS, BUT AT LEAST WITH THE ADVICE OF THE REGULATORY
11:26AM 12 AGENCY THAT SOMETHING UNTOWARD COULD HAPPEN? DOES THAT MOVE
11:26AM 13 THE NEEDLE ANY BIT?

11:27AM 14 MR. FLEURMONT: YES, YOUR HONOR. THAT'S A
11:27AM 15 COMPLICATED HYPOTHETICAL SO I CAN TAKE IT IN PART.

11:27AM 16 THE COURT: SURE.

11:27AM 17 MR. FLEURMONT: SO I HEARD YOUR HONOR SAY IF WE
11:27AM 18 DON'T DO SOMETHING WE'RE GOING TO BE IN TROUBLE OR GET
11:27AM 19 SANCTIONS.

11:27AM 20 IF THERE'S NOT A STRICT, A SPECIFIC DIRECTIVE OR A
11:27AM 21 SPECIFIC GUIDANCE ON WHAT THAT SOMETHING IS, THEN, YOUR HONOR,
11:27AM 22 WE SUBMIT THAT THAT IS VOLUNTARY BECAUSE YOU'RE MAKING A
11:27AM 23 DECISION OF YOUR OWN FREE WILL TO FIX A PROBLEM.

11:27AM 24 THE COURT: SO HERE WAS THERE A TEN DAY NOTICE?

11:27AM 25 MR. FLEURMONT: THERE WAS A TEN DAY NOTICE, YES.

11:27AM 1 THE COURT: AND THEN THE ACTION WAS TAKEN BY THE
11:27AM 2 COMPANY?

11:27AM 3 MR. FLEURMONT: THREE MONTHS LATER, YOUR HONOR.

11:27AM 4 THE COURT: I SEE. SO DOES THAT CHANGE THINGS?

11:27AM 5 MR. FLEURMONT: NO, IT DOES NOT CHANGE THINGS FOR
11:27AM 6 OUR POSITION. IT HELPS US OUT. IT WAS MUCH LATER AFTER THE
11:27AM 7 TEN DAYS.

11:27AM 8 THE COURT: I SEE.

11:27AM 9 MR. FLEURMONT: BUT THE GOVERNMENT DOES TRY TO
11:27AM 10 SHOEHORN THIS VOLUNTARY/INVOLUNTARY DISTINCTION INTO THIS CASE
11:27AM 11 BY POINTING TO TWO ACTIONS.

11:27AM 12 THE FIRST IS CMS ITSELF. THE GOVERNMENT ARGUES THAT CMS
11:28AM 13 REQUIRED THERANOS TO VOID THEIR TESTS. AND THE PROBLEM WITH
11:28AM 14 THAT, AS YOUR HONOR JUST ALLUDED, THE TEN DAY REQUIREMENT. THE
11:28AM 15 ACTIONS WERE DONE. THEY WERE DONE -- THEY WERE EXPLAINED IN AN
11:28AM 16 APRIL 1ST LETTER, BUT THEY WERE DONE WELL AFTER THE TEN DAY
11:28AM 17 REQUIREMENT.

11:28AM 18 THE SECOND PROBLEM WITH THAT IS CRITICALLY THE
11:28AM 19 GOVERNMENT'S CMS WITNESS, MS. BENNETT, WHO WE HAVE HEARD A LOT
11:28AM 20 ABOUT TODAY, SHE SAID, AND I QUOTE, "THERANOS MADE THE DECISION
11:28AM 21 TO VOID TEST RESULTS. CMS DIDN'T TELL THEM TO DO THAT."
11:28AM 22 THAT'S AT EXHIBIT 34, DOCKET 584-3 AT 6. THAT'S AT THE SECOND
11:28AM 23 TO THE LAST LINE OF THAT PAGE.

11:28AM 24 THE COURT: I READ THAT IN YOUR PLEADINGS. YOU
11:28AM 25 POINT THAT OUT, THAT PARAGRAPH.

11:28AM 1 MR. FLEURMONT: AND THE GOVERNMENT TALKS ABOUT
11:28AM 2 CHERRY PICKING TESTIMONY. THAT'S ALL SHE SAYS ABOUT VOIDING.
11:28AM 3 THERE'S NO MORE CHERRIES TO PICK TO USE THAT ANALOGY.

11:28AM 4 SO SHE IS VERY CLEAR ON THAT POINT THAT IT WAS NOT
11:28AM 5 REQUIRED BY CMS.

11:28AM 6 OKAY. SO THEN THERE WAS A SECOND REQUIREMENT, ALLEGED
11:28AM 7 REQUIREMENT THAT THE GOVERNMENT POINTS TO. THAT'S
11:28AM 8 42 CFR 493.129(K).

11:29AM 9 THAT REQUIRES A LAB TO, WHEN ERRORS IN REPORTED PATIENT
11:29AM 10 TEST RESULTS ARE DETECTED, TO NOTIFY AND ISSUE CORRECTED
11:29AM 11 REPORTS.

11:29AM 12 THE PROBLEM WITH THAT IS THAT THERE ARE NO -- AS I'M SURE
11:29AM 13 YOUR HONOR IS VERY FAMILIAR WITH, THE VOIDING WAS DONE IN A
11:29AM 14 BLANKET FASHION WITHOUT AN ANALYSIS DONE ABOUT WHO WAS AFFECTED
11:29AM 15 AND WHO WASN'T.

11:29AM 16 THERANOS MADE A DECISION WHEN THEY WERE LOOKING BACK ON
11:29AM 17 THEIR PRIOR LAB PRACTICES THAT THIS WOULD BE SOMETHING THAT
11:29AM 18 THEY FELT THAT THEY SHOULD DO.

11:29AM 19 YOU COULD SEE HOW THAT COULD HAPPEN IN A COMPANY AS
11:29AM 20 YOUR HONOR JUST GAVE THAT HYPOTHETICAL WHEN YOU'RE UNDER
11:29AM 21 INVESTIGATION AND YOU'RE GOING BACK AND FORTH, YOU'RE
11:29AM 22 SCRUTINIZING THINGS AND YOU'RE LOOKING AT THINGS A LITTLE MORE
11:29AM 23 CLOSELY THAN YOU USUALLY WOULD.

11:29AM 24 AND A COMPANY MIGHT DECIDE, WELL, WE'RE NOT REQUIRED TO DO
11:29AM 25 THIS, BUT IT MIGHT BE GOOD PRACTICE. AS I SAID EARLIER, THE

11:29AM 1 RULE, I THINK, IS MEANT TO PROTECT THAT TYPE OF BEHAVIOR AND
11:30AM 2 MEANT TO ENCOURAGE THAT TYPE OF BEHAVIOR. SO BECAUSE THERE WAS
11:30AM 3 NO REQUIREMENT FOR ACTUALLY VOIDING AND BECAUSE UNDER THAT RULE
11:30AM 4 THERE WAS NOTHING ACTUALLY PROTECTED, THAT IS ALSO NOT A BASIS
11:30AM 5 FOR A REQUIREMENT IN THIS CASE.

11:30AM 6 SO THE LAST POINT I WANT TO MAKE ON THE REQUIREMENT IS THE
11:30AM 7 ISSUE ABOUT BURDEN, AND WE'VE TALKED ABOUT BURDEN SHIFTING A
11:30AM 8 LOT THROUGHOUT THESE DIFFERENT ARGUMENTS.

11:30AM 9 SO THE GOVERNMENT IN ITS OPPOSITION ESSENTIALLY SAYS THAT
11:30AM 10 IF MS. HOLMES CANNOT SHOW THAT VOIDING WAS VOLUNTARY, THEN SHE
11:30AM 11 DOES NOT GET THE BENEFIT OF THE RULE.

11:30AM 12 BUT AS YOUR HONOR KNOWS, IT'S THE PROPONENT OF THE
11:30AM 13 EVIDENCE WHO HAS THE BURDEN OF SHOWING THAT IT'S ADMISSIBLE,
11:30AM 14 AND SO IT'S THE GOVERNMENT'S BURDEN TO SHOW THAT RULE 407
11:30AM 15 DOESN'T APPLY, EVEN IF THERE'S ANOTHER EXCEPTION THAT IT WOULD
11:30AM 16 APPLY IF THE ACTIONS WERE INVOLUNTARY.

11:30AM 17 SO WE JUST WANT TO MAKE THAT CLEAR THAT IT'S THE
11:30AM 18 GOVERNMENT'S BURDEN TO SHOW THAT THESE ACTIONS WERE NOT
11:30AM 19 VOLUNTARY, NOT MS. HOLMES'S BURDEN TO SHOW THAT THEY WERE.

11:31AM 20 THE COURT: OKAY.

11:31AM 21 MR. FLEURMONT: JUST A COUPLE QUICK POINTS ABOUT
11:31AM 22 RELEVANCE AND PREJUDICE. MR. LOOBY, I THINK HE EXPLAINED THE
11:31AM 23 NONRELEVANT CMS REPORT AND KIND OF THE PROCEDURES THAT
11:31AM 24 FOLLOWED. SO I WILL JUST QUICKLY SAY THAT THIS IS NOT A CASE
11:31AM 25 ABOUT NEGLIGENT LAB PROCEDURES AND THERE'S THAT MISSING LINK

11:31AM 1 BETWEEN WHAT CMS DOES AND WHAT CMS FOUND AND THE ALLEGATIONS IN
11:31AM 2 THIS CASE.

11:31AM 3 THE LAST POINT ABOUT PREJUDICE IS THAT I WANTED TO POINT
11:31AM 4 THE COURT TO A DECISION UNITED STATES VERSUS PACIFIC GAS AND
11:31AM 5 ELECTRIC. THAT'S AT 178 F.SUPP. 3D 927. WE CITED THAT --

11:31AM 6 THE COURT: I THINK YOU HEARD ME SAY YESTERDAY
11:31AM 7 YOUNG MR. SCHENK WAS INVOLVED IN THAT CASE I THINK.

11:31AM 8 MR. FLEURMONT: HE WAS.

11:31AM 9 THAT'S CITED AT PAGE 8 OF OUR BRIEF. THE REASON I PAUSE
11:31AM 10 IS BECAUSE I WANT TO SAY WE THINK THE GOVERNMENT
11:31AM 11 MISCHARACTERIZED THAT CASE, WHICH IS A LITTLE HARD TO SAY WHEN
11:31AM 12 THE PERSON IS RIGHT NEXT TO YOU WHO ACTUALLY ARGUED THAT CASE.

11:31AM 13 BUT THE GOVERNMENT CHARACTERIZED THIS CASE WAS JUST ONE
11:32AM 14 ABOUT PENALTIES AND ABOUT SANCTIONS AND SAYS THAT THE CASE
11:32AM 15 ESSENTIALLY SAYS THAT. THAT CAN BE PREJUDICIAL WHEN YOU
11:32AM 16 INCLUDE EVIDENCE OF PENALTIES BECAUSE IT HAS A RISK OF THE JURY
11:32AM 17 THINKING, WELL, YOU KNOW, IF A GOVERNMENT ENTITY PENALIZES
11:32AM 18 FIRST AND ISSUED A SANCTION, THEY MUST HAVE FOUND WHAT THE JURY
11:32AM 19 IS SUPPOSED TO FIND, AND SO THEY'RE SUBSTITUTING THEIR JUDGMENT
11:32AM 20 FOR THAT.

11:32AM 21 BUT THE CASE IS NOT JUST ABOUT SANCTIONS. JUST TO BE
11:32AM 22 CLEAR, THE CASE IS TALKING ABOUT REMEDIAL MEASURES. I JUST
11:32AM 23 WANT TO POINT THE COURT TO PAGE 49 OF THAT OPINION WHERE THE
11:32AM 24 COURT SAYS -- THEY'RE TALKING ABOUT THE CALIFORNIA PUBLIC
11:32AM 25 UTILITIES COMMISSION. THE COMMISSION'S ARGUMENT THAT THE

1 PENALTIES SHOULD BE EXCLUDED UNDER RULE 403 BECAUSE, QUOTE,
2 "THE COMMISSION'S CONCLUSIONS WOULD UNFAIRLY ENCOURAGE THE JURY
3 TO ADVOCATE ITS CRITICAL ROLE AS FACT FINDER APPLIED WITH EQUAL
4 FORCE TO THE COMMISSION'S REMEDIAL MEASURES."

5 THE COURT GOES ON TO SAY, "THERE IS A SUBSTANTIAL RISK
6 THAT THE JURY MAY ASSUME THAT IF THE COMMISSION, AUTHORITATIVE
7 GOVERNMENT AGENCY, IMPOSED REMEDIAL MEASURES ON PG&E, THEN PG&E
8 WAS DESERVING A PUNISHMENT."

9 AND, YOUR HONOR, WE SUBMIT THE SAME RISK IS IN THIS CASE
10 THANK YOU.

11 THE COURT: THANK YOU. MR. LEACH.

12 MR. LEACH: THANK YOU, YOUR HONOR. GOOD MORNING
13 AGAIN.

14 RULE 407 DOES NOT APPLY FOR AT LEAST THREE REASONS.

15 FIRST, THERANOS'S VOIDING OF ALL OF ITS EDISON TESTS IS
16 NOT A MEASURE WITHIN THE MEANING OF THE RULE. THE DEFENDANT
17 ARGUES IN ITS REPLY BRIEF THAT THE GOVERNMENT CONCEDES THAT IT
18 WAS A SUBSEQUENT REMEDIAL MEASURE. WE DO NOT. WE SAY THIS ON
19 PAGE 7 IN NOTE 5.

20 THE VOIDING OF THE TEST IS NOT A MEASURE. IT'S NOT THE
21 SAME THING AS A COMPANY PUTTING UP A CONE THAT SAYS "WET FLOOR
22 HERE, BE CAREFUL." IT'S NOT THE SAME THING AS CHANGING THE
23 DESIGN OF A PRODUCT TO MAKE IT SAFER. IT'S NOT THE SAME THING
24 AS FIRING AN EMPLOYEE. IT'S AN ADMISSION THAT WHAT I SAID
25 BEFORE I CAN NO LONGER SAY.

1 AND THEY'RE ESSENTIALLY TRYING TO IMMUNIZE THE DEFENDANT
2 FROM ALL OF THE STATEMENTS SHE MADE ABOUT HER LAB IN 2016.
3 THIS IS NOT A MEASURE WITHIN THE MEANING OF THE RULE. IT HAD
4 NO TENDENCY TO CORRECT ANY HARM. MANY OF THE TESTS THAT THEY
5 VOIDED WERE FROM 2014 AND 2015. SO THIS DECISION TO VOID THE
6 TEST IS YEARS AFTER THE FACT. IT HAD NO TENDENCY TO ACTUALLY
7 CORRECT ANY HARM.

8 AND I THINK THE COURT'S DESCRIPTION EARLIER ABOUT IS THIS
9 THE SAME THING AS, YOU KNOW, A COMPANY MAKING A PROSPECTIVE
10 DESIGN TO ITS PRODUCT, WHICH WE WANT TO ENCOURAGE, VERSUS A
11 BOARD OF DIRECTORS OR CEO DECIDING WHAT TO DO WHEN THE
12 REGULATORS COME LOOKING. THEY ARE NOT THE SAME THING. THIS IS
13 NOT A MEASURE WITHIN THE MEANING OF THE RULE.

14 AND I THINK IF MY FRIEND ON THE OTHER SIDE, IF THEIR
15 ARGUMENT IS ADOPTED, IT WOULD ESSENTIALLY IMMUNIZE A DEFENDANT
16 FROM HER OWN STATEMENTS MADE AFTER THERE'S SOME SCRUTINY ON HER
17 CONDUCT.

18 THE SECOND REASON RULE 407 DOES NOT APPLY IS THAT THIS WAS
19 NOT VOLUNTARY, AND IT'S NOT VOLUNTARY FOR A NUMBER OF REASONS.

20 FIRST OF ALL, THERANOS WAS UNDER AN OBLIGATION TO
21 COOPERATE WITH CMS. THAT'S IN 42 CFR 493.129(1)(K). SO THEY
22 HAD TO COOPERATE WITH THIS INSPECTION.

23 IN ADDITION, BECAUSE OF THIS IMMEDIATE JEOPARDY FINDING,
24 AND I'VE TALKED ABOUT THIS IN MY PRIOR ARGUMENT, THEY WERE
25 REQUIRED TO ACT. THEY HAD TO DO SOMETHING UNDER THE

11:36AM 1 REGULATION.

11:36AM 2 WHEN SARAH BENNETT SAYS WE DIDN'T TELL THEM WHAT TO DO,
11:36AM 3 THAT'S CORRECT, THEY DIDN'T TELL THEM EXACTLY WHAT TO DO. BUT
11:36AM 4 THEY NEEDED TO DO SOMETHING, AND IT WAS ON THERANOS TO DO
11:36AM 5 SOMETHING BECAUSE OF THAT LEGAL REQUIREMENT.

11:36AM 6 AND THE THIRD LEGAL REQUIREMENT THAT IS VERY IMPORTANT
11:36AM 7 HERE IS I MAY HAVE -- THE THIRD LEGAL REQUIREMENT IS THE ONE
11:36AM 8 NOT THAT SARAH BENNETT ORDERS, BUT IT EXISTS, AND IT'S A RULE
11:36AM 9 THAT SAYS IF YOU DETECT ERRORS IN YOUR TESTS ESSENTIALLY YOU
11:37AM 10 MUST FIX THEM.

11:37AM 11 NOW, THEY SAY WE CAN'T MEET OUR BURDEN TO SHOW THEY
11:37AM 12 DETECTED THE ERROR OR THAT THIS REGULATION ACTUALLY APPLIES,
11:37AM 13 AND THEY POINT TO SELF-SERVING STATEMENTS THAT MS. HOLMES MAKES
11:37AM 14 ABOUT DOING THIS OUT OF AN ABUNDANCE OF CAUTION.

11:37AM 15 BUT IN THAT SAME BREADTH HER OWN WORDS ARE WE DID THIS
11:37AM 16 BECAUSE WE WERE DISSATISFIED WITH OUR QUALITY ASSESSMENT
11:37AM 17 PROGRAM.

11:37AM 18 IN ADDITION, THE LAB DIRECTOR AT THE TIME, THE INDIVIDUAL
11:37AM 19 THAT MS. HOLMES HIRED IN LATE 2015 OR 2016, DR. KINGSHUK DAS
11:37AM 20 SAYS, HE CONCLUDED THE EDISON DEVICES NEVER PERFORMED THE LEVEL
11:37AM 21 OF ACCURACY AND PRECISION REQUIRED AND COULD NOT HAVE GENERATED
11:37AM 22 ANY RESULTS WHICH HAD CLINICAL VALUE.

11:37AM 23 DAS SAID THERE WAS SOME PUSHBACK, BUT THIS CONCLUSION WAS
11:38AM 24 BASED ON SIX SIGNA METRICS.

11:38AM 25 THERANOS MANAGEMENT SUGGESTED THIS WAS NOT A DEVICE ISSUE

11:38AM 1 BUT RATHER A QUALITY SYSTEM ISSUE.

11:38AM 2 DAS DISAGREED WITH THAT ASSESSMENT AND DECIDED TO VOID ALL
11:38AM 3 EDISON TESTS.

11:38AM 4 DAS SAID IT WAS HIS OBLIGATION AS THE DIRECTOR OF RECORD
11:38AM 5 TO CONDUCT A PATIENT ASSESSMENT TO DETERMINE IF ANY HARM CAME
11:38AM 6 FROM A LABORATORY ERROR, AND HE DID THAT.

11:38AM 7 DR. DAS WILL TELL YOU, YOUR HONOR, THAT THIS WAS NOT
11:38AM 8 VOLUNTARY, THAT HE FELT THAT HE HAD TO DO THIS BECAUSE OF THE
11:38AM 9 REG, BECAUSE OF PATIENT SAFETY, AND BECAUSE IT WAS THE RIGHT
11:38AM 10 THING TO DO.

11:38AM 11 SO WHOEVER HAS THE BURDEN HERE, AND WHEN I WAS TALKING
11:38AM 12 ABOUT BURDEN IN THE BRIEF I WAS USING THE LANGUAGE FROM THE
11:38AM 13 PG&E CASE WHERE THE CPUC STARTS ASKING QUESTIONS AND THERE'S A
11:39AM 14 LITTLE AMBIGUITY ABOUT WHY PG&E IS DOING WHAT AND THE COURT
11:39AM 15 SAYS BASED ON THE RECORD BEFORE ME AND IT'S OBVIOUS BASED ON
11:39AM 16 THE TOTALITY OF THE FACTS THAT PG&E IS NOT DOING THIS JUST
11:39AM 17 BECAUSE IT'S A GOOD CORPORATE CITIZEN, IT'S DOING THIS BECAUSE
11:39AM 18 A REGULATORY AUTHORITY IS LOOMING OVER IT.

11:39AM 19 AND BY THE WAY, IN THIS CASE WE HAVE A REG THAT THEY HAVE
11:39AM 20 TO COMPLY WITH IF THEY DETECT ERRORS. SO THIS WAS NOT
11:39AM 21 VOLUNTARY IN ANY WAY. THIS IS NOT SOME GOOD CORPORATE CITIZEN
11:39AM 22 DECIDING TO DO THE RIGHT THING PROACTIVELY TO FIX THE DEVICE OR
11:39AM 23 TO DO SOMETHING. THIS IS AN ADMISSION. THIS IS AN ADMISSION
11:39AM 24 THAT I CANNOT SAY MY TESTS ARE CORRECT.

11:39AM 25 THE THIRD REASON WHY RULE 407 DOES NOT APPLY HERE IS

11:39AM 1 BECAUSE IT ONLY APPLIES TO MEASURES, YOUR HONOR. IT APPLIES TO
11:39AM 2 THE ACTUAL ACT, IT APPLIES TO THE PUTTING UP THE CONE TO MAKE
11:39AM 3 SURE SOMEONE DOESN'T SLIP ON THE FLOOR, IT APPLIES TO THE
11:40AM 4 PROSPECTIVE CHANGING OF THE SAFETY DEVICE, AND IT APPLIES TO A
11:40AM 5 DISCHARGE OF AN EMPLOYEE. WE KNOW THAT FROM THE ADVISORY
11:40AM 6 COMMITTEE NOTES IN THE RULE.

11:40AM 7 IT DOES NOT APPLY TO A COMPANY'S INTERNAL ANALYSIS, ITS
11:40AM 8 OWN AFTER-THE-FACT INVESTIGATION OF WHAT HAPPENED OR ITS
11:40AM 9 STATEMENTS ABOUT WHAT HAD HAPPENED. IT DOESN'T APPLY TO THE
11:40AM 10 ANALYSIS. IT APPLIES ONLY TO THE MEASURE.

11:40AM 11 AND WE CITED A TENTH CIRCUIT CASE AND AN EIGHTH CIRCUIT
11:40AM 12 CASE FOR THAT PROPOSITION. IN THE REPLY THEY COME BACK WITH A
11:40AM 13 CASE CALLED MADDOX VERSUS CITY OF LOS ANGELES AND SAY THAT THE
11:40AM 14 RULE IS SOMEHOW DIFFERENT IN THE NINTH CIRCUIT. IT'S NOT.
11:40AM 15 THAT'S THE RULE IN THE NINTH CIRCUIT THAT I JUST DESCRIBED.

11:40AM 16 MADDOX INVOLVED A DISCIPLINARY PROCEEDING AGAINST A POLICE
11:40AM 17 OFFICER IN A USE OF FORCE CASE. AND DISCIPLINARY PROCEEDINGS
11:41AM 18 ARE EXACTLY LIKE THE FIRING OF AN EMPLOYEE THAT YOU SEE IN THE
11:41AM 19 ADVISORY COMMITTEE NOTES.

11:41AM 20 MS. HOLMES'S STATEMENTS AND THERANOS STATEMENTS TO CMS IN
11:41AM 21 RESPONSE TO THIS INSPECTION ARE NOT THE SAME THING. THEIR
11:41AM 22 ANALYSIS ABOUT WHAT HAPPENED WITH THE EDISON DEVICE IS NOT THE
11:41AM 23 SAME THING.

11:41AM 24 AND IT'S NOT JUST ME SAYING THAT. THERE ARE PLENTY OF
11:41AM 25 DISTRICT COURT CASES LOOKING AT MADDOX. MADDOX WAS A 1988

11:41AM 1 CASE. THERE ARE PLENTY OF DISTRICT COURT CASES THAT ADOPT THIS
11:41AM 2 READING OF MADDOX THAT IT APPLIES ONLY TO THE DISCHARGE OF THE
11:41AM 3 EMPLOYEE OR A DISCIPLINARY PROCEEDING AND NOT AN AFTER-THE-FACT
11:41AM 4 INVESTIGATION INTO WHAT HAPPENED.

11:41AM 5 AND MY CITES FOR THOSE ARE AGUILAR VERSUS CITY OF
11:41AM 6 LOS ANGELES. THIS IS AN UNPUBLISHED NINTH CIRCUIT CASE FROM
11:41AM 7 MARCH 26TH, '21, 2021 WESTLAW 1157922.

11:42AM 8 ANOTHER CASE WHERE YOU CAN SEE THIS DISTINCTION BETWEEN
11:42AM 9 DISCIPLINARY PROCEEDINGS AND INTERNAL ANALYSIS OF WHAT HAPPENED
11:42AM 10 AFTER-THE-FACT INVESTIGATIONS TO DETERMINE WHAT HAPPENED,
11:42AM 11 ANOTHER GOOD CASE FOR THAT IS -- EXCUSE ME -- A CASE INVOLVING
11:42AM 12 THE CITY OF MILWAUKEE, 249 F.SUPP. 3D 920, AND THAT CASE FROM
11:42AM 13 THE EASTERN DISTRICT OF WISCONSIN CITES A DISTRICT OF OREGON
11:42AM 14 CASE, ARANDA VERSUS CITY OF MCMINNIVILLE, 942 F.SUPP. 2D 1096.

11:42AM 15 SO THE MADDOX CASE CAME UP IN THE REPLY. I URGE THE
11:42AM 16 COURT TO SHEPARDIZE THAT BECAUSE I DON'T THINK IT BEARS THE
11:42AM 17 WEIGHT THAT MY FRIENDS ON THE OTHER SIDE WOULD ASCRIBE TO IT.

11:42AM 18 THERE'S ONE OTHER THING I WANT TO MAKE CLEAR. THEY KEEP
11:42AM 19 SAYING THIS IS A SMALL NUMBER OF TESTS. THERE SHOULD BE NO
11:43AM 20 MISUNDERSTANDING ABOUT WHAT THEY DID. THEY VOIDED EVERY SINGLE
11:43AM 21 TEST RUN ON ITS EDISON DEVICE. EVERY SINGLE ONE. THEY WERE
11:43AM 22 NOT EVEN IN A POSITION TO SAY THESE ONES WERE OKAY BUT THESE
11:43AM 23 ONES WEREN'T OKAY. THAT'S HOW BAD IT WAS.

11:43AM 24 SO THIS IS NOT SOME SMALL UNIVERSE. THIS IS EVERY TEST
11:43AM 25 THAT THEY RAN ON WHAT THEY SAID WAS THEIR PATH BREAKING

11:43AM 1 INVENTION. THIS IS VERY RELEVANT EVIDENCE. 407 IS NOT A BASIS
11:43AM 2 TO EXCLUDE IT.

11:43AM 3 FOR THE 403 CONSIDERATIONS HERE, IF MS. HOLMES HAS
11:43AM 4 ALTERNATIVE EXPLANATIONS FOR WHY THEY DID THIS, SHE CAN PRESENT
11:43AM 5 THAT. IF SHE THINKS THE GOVERNMENT IS MISREADING THIS ADD
11:43AM 6 ADMISSION, SHE CAN CROSS-EXAMINE WITNESSES ABOUT THAT. WE CAN
11:43AM 7 ASK DR. DAS EXACTLY WHY THERANOS VOIDED ALL OF ITS TESTS.

11:43AM 8 BUT THIS IS A DEEPLY RELEVANT ADMISSION. IT DOESN'T FIT
11:44AM 9 WITHIN 407. IT WOULD GIVE ANY FRAUDSTER WHO DOESN'T -- OR WHO
11:44AM 10 SAYS TO THE WORLD I'M NOT STANDING BY MY EARLIER STATEMENT SOME
11:44AM 11 TYPE OF PASS, AND THAT'S JUST NOT APPROPRIATE HERE. THIS IS
11:44AM 12 ADMISSIBLE EVIDENCE, AND THE COURT SHOULD DENY THE MOTION.

11:44AM 13 THE COURT: THANK YOU.

11:44AM 14 MR. FLEURMONT: YOUR HONOR, I'D LIKE TO START WITH
11:44AM 15 MR. LEACH'S CONTENTION THAT IT WAS NOT A REMEDIAL MEASURE.

11:44AM 16 THE GOVERNMENT'S WHOLE THEORY OF THIS CASE IS THAT
11:44AM 17 THERANOS PUT OUT TEST RESULTS THAT WEREN'T ACCURATE THAT
11:44AM 18 AFFECTED PEOPLE'S LIVES AND IT AFFECTED SOME OF THEIR
11:44AM 19 CONDITIONS.

11:44AM 20 AT THE SAME TIME I THINK I HEAR HIM SAYING NOW THAT
11:44AM 21 ISSUING A VOIDING OF THAT TEST, PROVIDING INFORMATION TO FOLKS,
11:45AM 22 THAT OUT OF AN ABUNDANCE OF CAUTION TO NOT USE THAT FOR PATIENT
11:45AM 23 RESULTS IS NOT A MEASURE THAT WOULD -- IF I COULD JUST GO
11:45AM 24 STRAIGHT TO THE RULE -- A MEASURE TAKEN THAT WOULD HAD MADE AN
11:45AM 25 EARLIER INJURY OR HARM LESS LIKELY TO OCCUR, WHICH I THINK IS

11:45AM 1 THAT POSITION.

11:45AM 2 THEIR THEORY OF THE CASE IS INCONSISTENT WITH ACTUALLY
11:45AM 3 WHAT THE RULE REQUIRES. THIS IS A MEASURE TAKEN TO MAKE AN
11:45AM 4 INJURY LESS LIKELY TO OCCUR. SO WE DO THINK THAT IT DOES FALL
11:45AM 5 UNDER RULE 407 AS A REMEDIAL MEASURE.

11:45AM 6 THE SECOND POINT I'D LIKE TO DISCUSS IS MR. LEACH SAYS ON
11:45AM 7 ONE HAND THAT THERE WAS A REGULATION THAT IF YOU DETECT AN
11:45AM 8 ERROR, YOU'RE SUPPOSED TO CORRECT IT. BUT ON THE OTHER HAND,
11:45AM 9 THEY DIDN'T DETECT ANY ERRORS BECAUSE THEY COULDN'T TELL.
11:45AM 10 THOSE ARE ALSO TWO VERY INCONSISTENT POSITIONS.

11:45AM 11 AS A LETTER ON APRIL 1ST, WHICH IS EXHIBIT 27, SIGNED BY
11:46AM 12 DR. DAS, WHO HE REFERENCES, SAYS THAT THE TESTS WERE TAKEN OUT
11:46AM 13 OF -- THE VOIDING WAS DONE OUT OF AN ABUNDANCE OF CAUTION. IT
11:46AM 14 WAS NOT RELATED TO ANY FINDING OF PATIENT HARM.

11:46AM 15 SO THE BEST AUTHORITY THAT WE BELIEVE ON THIS IS THE
11:46AM 16 GOVERNMENT'S WITNESS SARAH BENNETT WHO IS FROM CMS AND MADE
11:46AM 17 THAT STATEMENT THAT IT WAS NOT REQUIRED TO VOID TESTS.

11:46AM 18 AND ON THE LAST -- THE LAST POINT I'D LIKE TO MAKE IS THAT
11:46AM 19 MR. LEACH POINTS TO SEVERAL OBLIGATIONS THAT I POINTED TO AS
11:46AM 20 REQUIREMENTS, BUT NONE OF THEM WERE VOIDING. SO THE OBLIGATION
11:46AM 21 TO COOPERATE IS UNCONTESTED. WE KNOW THEY HAVE AN OBLIGATION
11:46AM 22 TO COOPERATE.

11:46AM 23 THE OBLIGATION TO RESPOND TO THE FINDING WITHIN TEN DAYS
11:46AM 24 IS ALSO NOT CONTESTED. WE KNEW THEY HAD THAT OBLIGATION.

11:46AM 25 I DID NOT HEAR HIM SAY THAT ANY OF THOSE REQUIREMENTS IN

11:46AM 1 CMS REQUIRED THE VOIDING, WHICH I THINK IS A CRITICAL POINT.

11:46AM 2 THE COURT: OKAY.

11:47AM 3 MR. FLEURMONT: NO FURTHER QUESTIONS?

11:47AM 4 THE COURT: MR. LEACH, ANYTHING ELSE?

11:47AM 5 MR. LEACH: VERY BRIEFLY, YOUR HONOR.

11:47AM 6 THE COURT: WE CAN DO A LITTLE POINT, COUNTERPOINT.

11:47AM 7 I FIND THAT VERY HELPFUL. THANK YOU.

11:47AM 8 MR. LEACH: WE ARE SAYING THAT THE REGS REQUIRED THE
11:47AM 9 VOIDING OF THE TESTS. WE ARE ABSOLUTELY SAYING THAT. AND IT'S
11:47AM 10 NOT JUST THAT ONE REGULATORY REQUIREMENT THAT MAKES IT PLAINLY
11:47AM 11 EVIDENCE THAT THIS IS NOT THERANOS'S CORPORATE GOOD GRACES. IT
11:47AM 12 IS THE FACT THAT IT WAS IN RESPONSE TO THE IMMEDIATE JEOPARDY
11:47AM 13 FINDING AND THEIR OBLIGATION. SO IT'S ALL THREE WORKING
11:47AM 14 TOGETHER, BUT WE ABSOLUTELY CONTEND THAT THEY WERE REQUIRED
11:47AM 15 UNDER THAT THIRD REGULATION TO CORRECT THE TEST.

11:47AM 16 AND MY POINT ON, YOU KNOW, MY POINT ON THE VOIDING IS NOT
11:47AM 17 THEY COULDN'T TELL. THEY CAN'T TELL YOU IF IT'S A VALUE OF 50
11:47AM 18 VERSUS A VALUE OF 100. THEY JUST THREW UP THEIR HANDS. THAT'S
11:47AM 19 MY POINT THAT THEY COULDN'T TELL.

11:47AM 20 MR. FLEURMONT: I GUESS MY LAST POINT, YOUR HONOR,
11:47AM 21 IS THAT THIS IDEA THAT THEY COULDN'T TELL, AND THIS IS GOING
11:47AM 22 BACK TO MY HYPOTHETICAL OF A CORPORATION THAT LOOKS BACK AT ITS
11:48AM 23 PROCESSES AND SAYS, HEY, WE CAN DO A LITTLE BIT BETTER, LET'S
11:48AM 24 DO A LITTLE BIT BETTER. IT DOESN'T NECESSARILY MEAN THAT THEY
11:48AM 25 HAVE DONE ANYTHING WRONG, BUT THEY SEE AN IMPROVEMENT THAT THEY

11:48AM 1 CAN MAKE. AND THAT WAS THE CASE IN THIS CASE.

11:48AM 2 MR. LEACH: WHAT IMPROVEMENT, YOUR HONOR? WHAT
11:48AM 3 IMPROVEMENTS IN THE EDISON DID THEY DO? THEY ISSUED A PIECE OF
11:48AM 4 PAPER THAT VOIDED THE TESTS TO ALL OF THE EDISON PATIENTS.

11:48AM 5 AND EVEN IF THAT WERE A MEASURE, IT WOULDN'T APPLY TO
11:48AM 6 THEIR OWN INTERNAL CONCLUSIONS ABOUT WHAT EDISON COULD DO.

11:48AM 7 THE COURT: YOU GET THE LAST WORD.

11:48AM 8 MR. FLEURMONT: YOUR HONOR, I THINK THE LETTER MAKES
11:48AM 9 VERY CLEAR THAT THERE WAS A DISSATISFACTION WITH SOME LAB
11:48AM 10 PRACTICES AND THE IMPROVEMENT WAS IMPROVING THOSE LAB
11:48AM 11 PRACTICES.

11:48AM 12 THE COURT: I SEE.

11:48AM 13 MR. FLEURMONT: AND, YOU KNOW FOR THE REASONS IN OUR
11:48AM 14 PAPERS AND THE REASONS I'VE SAID TODAY, WE THINK RULE 407
11:48AM 15 CLEARLY APPLIES AND THE EVIDENCE OF VOIDING SHOULD BE EXCLUDED.

11:48AM 16 IF THE COURT DISAGREES THIS EVIDENCE IS HIGHLY
11:48AM 17 PREJUDICIAL, UNFAIRLY PREJUDICIAL, AND IT SHOULD BE EXCLUDED
11:48AM 18 UNDER RULE 403.

11:48AM 19 THANK YOU.

11:49AM 20 THE COURT: THANK YOU VERY MUCH.

11:49AM 21 MR. LEACH: THANK YOU, YOUR HONOR.

11:49AM 22 THE COURT: WE'RE PERILOUSLY CLOSE TO THE NOON HOUR.
11:49AM 23 WHY DON'T WE TAKE OUR LUNCH BREAK NOW, AND WE'LL COME BACK AT
11:49AM 24 ABOUT 1:00 O'CLOCK, PLEASE, 1:00 O'CLOCK. GREAT.

11:49AM 25 THE CLERK: COURT IS IN RECESS UNTIL 1:00 P.M. THIS

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LINE SHALL TERMINATE.

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(LUNCH RECESS TAKEN AT 11:49 A.M.)

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AFTERNOON SESSION

(COURT CONVENED AT 1:11 P.M.)

THE COURT: ALL RIGHT. WE'RE BACK ON THE RECORD IN THE HOLMES MATTER. ALL PARTIES PREVIOUSLY PRESENT ARE PRESENT ONCE AGAIN. WE'LL CONTINUE OUR DISCUSSION ON THE MOTIONS IN LIMINE.

LET'S SEE. I THINK WE ARE -- ARE WE AT 573 NOW? I BELIEVE THAT'S WHERE WE ARE AT. IT'S MS. HOLMES'S MOTION TO EXCLUDE THE FDA 2015 INSPECTION EVIDENCE.

I LOOK AT THIS AND IT APPEARS, MR. LOOBY, YOU'RE APPEARING TO ADVANCE THIS MOTION.

MR. LOOBY: THAT'S CORRECT, YOUR HONOR.

THE COURT: AND IT LOOKS LIKE WE'RE GOING TO HAVE A LITTLE DÉJÀ VU ABOUT OUR CONVERSATIONS ABOUT 803, IS THAT FAIR?

MR. LOOBY: THAT'S CORRECT, YOUR HONOR. I'M BACK WITH ANOTHER INSPECTION, A DIFFERENT AGENCY, AND KIND OF THE SAME HEARSAY ISSUES.

THE COURT: RIGHT.

MR. LOOBY: SO I THINK WE'LL SAVE A BIT OF TIME ADDRESSING THAT. I WILL ADDRESS SOME OF THE UNIQUE FACTS AS THEY APPLY TO THE FDA INSPECTION DOCUMENTS, BUT I THINK WE HAVE GONE OVER THE BASICS OF THE ARGUMENT.

THE COURT: OKAY. UNLESS THERE ARE ANY NEW CASES THAT HAVE COME DOWN IN THE LAST HOUR OR ANYTHING ELSE EITHER SIDE WANT TO BRING TO MY ATTENTION. AND I'M HAPPY TO HEAR.

01:13PM 1 I'M NOT TRYING TO FORECLOSE ANY FURTHER DEVELOPMENT ABOUT THAT
01:13PM 2 ISSUE. IT'S AN INTERESTING ISSUE.

01:13PM 3 MR. LOOBY: YES.

01:13PM 4 THE COURT: OKAY. THANK YOU.

01:13PM 5 MR. LOOBY: THANK YOU, YOUR HONOR.

01:13PM 6 I THINK A LITTLE BACKGROUND CAN BE HELPFUL ABOUT THE FDA'S
01:13PM 7 ROLE IN THE CASE. SO, AS YOUR HONOR KNOWS, THERE'S AN
01:13PM 8 INDICTMENT ALLEGATION THAT CONCERNS THE FDA, AND THAT
01:13PM 9 ALLEGATION IS THAT MS. HOLMES, SHE TOLD INVESTORS THAT THERANOS
01:13PM 10 ANALYZER AND TEST DID NOT NEED FDA CLEARANCE OR APPROVAL WHEN
01:13PM 11 THE GOVERNMENT ALLEGES SHE KNEW THAT TO NOT BE THE CASE.

01:13PM 12 SO THE GOVERNMENT ALLEGES THAT THESE REPRESENTATIONS
01:13PM 13 HAPPENED IN 2013 AND 2014 PRINCIPALLY. IMPORTANTLY, KIND OF
01:13PM 14 THE LAST FUNDRAISING ROUND FOR INVESTORS IN THE CASE CLOSED IN
01:13PM 15 APRIL OF 2015.

01:13PM 16 THE FDA INSPECTION THAT WE'RE SET TO TALK ABOUT TODAY,
01:14PM 17 THAT BEGAN IN AUGUST OF 2015. SO MONTHS LATER.

01:14PM 18 AND BECAUSE OF THAT, NOTHING THAT HAPPENED DURING THAT
01:14PM 19 INSPECTION COULD BE RELEVANT TO THOSE FDA RELATED
01:14PM 20 REPRESENTATIONS ABOUT WHAT WAS REQUIRED OR WAS NOT REQUIRED IN
01:14PM 21 TERMS OF APPROVAL OR CLEARANCE.

01:14PM 22 THE GOVERNMENT IN ITS OPPOSITION DOESN'T DISPUTE THIS. IT
01:14PM 23 CONCEDES THERE'S NO CONNECTION BETWEEN THE FDA ALLEGATIONS IN
01:14PM 24 THE INDICTMENT AND THIS INSPECTION EVIDENCE BY IGNORING THAT
01:14PM 25 PART.

01:14PM 1 AND IT ACTUALLY DISCLAIMS ANY NEED TO TIE THE FDA
01:14PM 2 INSPECTION EVIDENCE TO ANY REPRESENTATION TO ANY SINGLE
01:14PM 3 INVESTOR. IT SAYS THAT THAT'S KIND OF BESIDE THE POINT.

01:14PM 4 SO WHAT ARE WE DOING HERE? THE GOVERNMENT NOW PROPOSES TO
01:14PM 5 USE THE FDA INSPECTION EVIDENCE IN A DIFFERENT WAY. IT WILL
01:14PM 6 ARGUE THAT IT SHOWS THAT THERANOS BLOOD COLLECTION DEVICE,
01:14PM 7 WHICH I'LL BE REFERRING TODAY AS A CTN, IT'S A CAPILLARY TO
01:15PM 8 NANOTAINER IS WHAT THE THREE LETTERS STAND FOR. SO HOPEFULLY
01:15PM 9 CTN IS EASY ENOUGH FOR TODAY.

01:15PM 10 THE GOVERNMENT IS GOING TO ALLEGE THAT THE INSPECTION
01:15PM 11 EVIDENCE SHOWED THAT THESE DIDN'T WORK VERY WELL. BUT THE FDA
01:15PM 12 INSPECTION EVIDENCE IS ACTUALLY NOT RELEVANT TO THAT QUESTION.

01:15PM 13 AND THE BRIEFING KIND OF GOES INTO WHAT THIS IS AT A HIGH
01:15PM 14 LEVEL, BUT WITH THE COURT'S INDULGENCE, I ACTUALLY THINK IT
01:15PM 15 BENEFITS US TO TAKE A COUPLE STEPS BACK.

01:15PM 16 SO WE TALKED EARLIER AT LENGTH ABOUT CLIA REGULATIONS AND
01:15PM 17 CMS. SO THAT'S THE BODY OF LAW THAT GOVERNS CLINICAL
01:15PM 18 LABORATORIES. THERANOS OPERATED A CLINICAL LABORATORY, SO IT
01:15PM 19 HAD TO ADHERE TO CLIA, AND IT WAS REGULATED BY CMS.

01:15PM 20 THE CLIA REGULATIONS SET FORTH A COMPREHENSIVE REGULATORY
01:15PM 21 SCHEME ABOUT LAB OPERATIONS BASICALLY FROM SOUP TO NUTS. THE
01:15PM 22 THERANOS BUSINESS MODEL WAS UNIQUE BECAUSE IT ALSO BUILT ITS
01:15PM 23 OWN DEVICES TO USE IN ITS CLIA LAB. THAT INCLUDES THE
01:16PM 24 ANALYZER, OR TSPU, ANOTHER ACRONYM, BUT MORE IMPORTANTLY FOR
01:16PM 25 THIS NOTION, WE'RE GOING TO BE TALK ABOUT THE CTN'S WHICH

01:16PM 1 THERANOS ALSO MANUFACTURED.

01:16PM 2 NORMALLY A COMPANY THAT MANUFACTURES A MEDICAL DEVICE AND
01:16PM 3 THEN SELLS THEM TO SOME OTHER LAB USER LIKE A COMPANY THAT
01:16PM 4 OPERATES A CLINICAL LAB, THEY'RE REGULATED EXCLUSIVELY BY FDA.

01:16PM 5 FDA, NOT SURPRISINGLY, HAS MANUFACTURING, DESIGN, AND
01:16PM 6 QUALITY REQUIREMENTS ALL OF ITS OWN. THESE ARE CALLED THE
01:16PM 7 QSR'S IN THE BRIEFING.

01:16PM 8 AND THESE GOVERN, YOU KNOW, THE TYPES OF DOCUMENTS THAT A
01:16PM 9 MANUFACTURER HAS TO KEEP, HOW IT HANDLES COMPLAINTS FROM THE
01:16PM 10 CONSUMERS, SO THE PERSON THAT YOU'RE SELLING THE DEVICE TO, HOW
01:16PM 11 IT ASSURES ITSELF BASICALLY OF THE QUALITY OF THE DEVICES THAT
01:16PM 12 IT'S MANUFACTURING THAT THEY'RE SUITABLE FOR THE INDICATIONS AT
01:16PM 13 WHICH THEY'RE APPROVED BY THE FDA.

01:16PM 14 SO THERANOS SITS AT THE MIDDLE OF THESE TWO OVERLAPPING
01:16PM 15 AND SOMEWHAT REDUNDANT REGULATORY SCHEMES, AND THE OBSERVATIONS
01:17PM 16 IN THE TWO FORM 438'S, WHICH ARE THE FDA KIND OF INSPECTION
01:17PM 17 REPORTS.

01:17PM 18 I'LL START OVER. THE OBSERVATIONS IN THE TWO FORM 438'S,
01:17PM 19 THEY ALL EMERGE FROM THE SAME DISCONNECT BETWEEN THE FDA AND
01:17PM 20 THERANOS ABOUT HOW THESE TWO BODIES OF LAW WOULD APPLY TO
01:17PM 21 THERANOS'S BUSINESS.

01:17PM 22 SO THERANOS BELIEVED THAT IT WAS OFFERING TESTS INCLUDING
01:17PM 23 THOSE RUN ON BLOOD SAMPLES COLLECTED AND TRANSPORTED IN THE
01:17PM 24 CTN'S AS LABORATORY DEVELOPED TESTS. THIS HAS BEEN POPPING UP
01:17PM 25 IN THE BRIEFING FROM TIME TO TIME.

01:17PM 1 LABORATORY DEVELOPED TESTS, I GUESS THE ROUGH DEFINITION
01:17PM 2 IS THAT IT IS A TEST THAT A CLINICAL LABORATORY KIND OF
01:17PM 3 MANUFACTURES IN HOUSE. IT DOESN'T SOURCE MATERIALS FROM
01:17PM 4 OUTSIDE.

01:17PM 5 SO FDA AS A MATTER OF POLICY HISTORICALLY HAS NOT
01:18PM 6 REGULATED LDT'S. IT'S EMBRACED THE POSITION, THE POSTURE OF
01:18PM 7 KIND OF FORBEARANCE ON THAT. IT STILL DOESN'T. INSTEAD, THE
01:18PM 8 PERFORMANCE OF LTD'S FALLS TO CLIA AND CMS.

01:18PM 9 SO THE FDA KNEW THAT THERANOS BELIEVED ITS TESTS WERE
01:18PM 10 LDT'S BECAUSE THERANOS TOLD THEM SO OVER AND OVER AGAIN. AND
01:18PM 11 THE BEST THING TO LOOK AT FOR THIS FACT IS ACTUALLY THE FDA'S
01:18PM 12 INSPECTION REQUEST FORM.

01:18PM 13 SO I'LL KINDLY ASK MS. SAHARIA TO PULL UP DEFENSE
01:18PM 14 EXHIBIT 82, AND THAT'S AT ECF 231-1 FOR THE RECORD. THIS IS
01:18PM 15 THE AUGUST 2015 INSPECTION FORM.

01:18PM 16 SO WHILE THAT'S PULLING UP, THIS BASICALLY SETS OUT THE
01:18PM 17 SCOPE OF THE REVIEW FOR THE INSPECTORS WHO ARE GOING TO BE
01:18PM 18 GOING IN AT THE END OF AUGUST OF 2015 TO REVIEW THERANOS'S
01:19PM 19 MANUFACTURING FACILITIES.

01:19PM 20 THE COURT: WAS THIS AN INSPECTION AT THERANOS'S
01:19PM 21 REQUEST?

01:19PM 22 MR. LOOBY: NO. THIS IS A FOR CAUSE INSPECTION THAT
01:19PM 23 WAS INITIATED BY THE FDA AND ACTUALLY MORE OR LESS UNANNOUNCED.

01:19PM 24 SO UNLIKE THE CMS, WHICH WAS ALSO KIND OF FOR CAUSE AND
01:19PM 25 APART BUT ALSO PARTIALLY A ROUTINE RECERTIFICATION SURVEY, THIS

01:19PM 1 IS A FOR CAUSE INSPECTION BASED ON COMPLAINTS THAT THE FDA HAD
01:19PM 2 RECEIVED AND OTHER THINGS WHICH I'LL GET INTO IN WALKING US
01:19PM 3 THROUGH THIS INSPECTION REQUEST FORM.

01:19PM 4 SO, MS. SAHARIA, IF WE CAN GO TO PAGE 3 TO 4. AND THERE'S
01:19PM 5 A SECTION CALLED OBJECTIVES.

01:19PM 6 MS. SAHARIA: THE NEXT PAGE?

01:19PM 7 MR. LOOBY: I THINK IT'S LIKE AT THE BREAK BETWEEN
01:19PM 8 ECF 3 AND ECF 4.

01:20PM 9 YES. SO THIS LISTS THE REGULATORY PROVISIONS THAT THE
01:20PM 10 AGENCY IS GOING TO GO IN AND SEE KIND OF WHAT APPLIES. AND
01:20PM 11 THAT FIRST ONE QUALITY SYSTEMS IS PART -- IS THE QSR, AND THE
01:20PM 12 OTHERS ARE ALL ABOUT MEDICAL DEVICE, KIND OF MANUFACTURING AND
01:20PM 13 RECORDKEEPING FOR MANUFACTURERS.

01:20PM 14 IF WE GO TO ECF PAGE 5 AND HERE UNDER THE NUMBER 6 THE
01:20PM 15 FIRST BIG PARAGRAPH IT SAYS, "THERANOS BELIEVES THAT BECAUSE IT
01:20PM 16 IS CURRENTLY PERFORMING ALL SAMPLE TESTING IN ITS CLIA LAB ITS
01:20PM 17 TESTING OF SAMPLES WITH VARIOUS ANALYZERS ASSAYS/ANALYTES USING
01:20PM 18 ITS MANUFACTURED ANALYZER ARE LABORATORY DEVELOPED TESTS." SO
01:20PM 19 THIS REFLECTS THE FDA'S UNDERSTANDING OF THERANOS'S REGULATORY
01:21PM 20 POSITION.

01:21PM 21 AND IF WE GO TO ECF PAGE 6 UNDER REASON FOR INSPECTION.
01:21PM 22 IT SAYS, "CDRH," AND THAT'S A DIVISION WITHIN THE FDA, "IS
01:21PM 23 CONCERNED THAT THE FIRM MAY NOT HAVE ADEQUATE DESIGN CONTROL
01:21PM 24 PROCEDURES, COMPLAINT HANDLING AND INVESTIGATION PROCEDURES,
01:21PM 25 AND MDR," SO MEDICAL DEVICE REPORTING, "PROCEDURES GIVEN THAT

01:21PM 1 THE FIRM BELIEVES IT IS AN LDT PROVIDER, NOT A MANUFACTURER
01:21PM 2 SUBJECT TO FDA REGULATIONS."

01:21PM 3 SO THIS IS WHAT THE FDA WENT IN LOOKING FOR, QSR, FDA
01:21PM 4 SPECIFIC POLICIES AND DOCUMENTATION RELATING TO THE CTN'S,
01:21PM 5 WHICH BECAUSE OF THEIR INTERACTIONS WITH THERANOS, THEY
01:21PM 6 SUSPECTED THE COMPANY MIGHT NOT HAVE.

01:21PM 7 NOW, THERANOS DID HAVE DOCUMENTATION AND DATA ON
01:21PM 8 MANUFACTURING AND DESIGN OF THE CTN'S, AND IT DID HAVE RECORDS
01:22PM 9 TO SHOW HOW IT DEALT WITH COMPLAINTS, SO SOME OF THESE SAME
01:22PM 10 TOPICS THAT THESE REGULATIONS HIT, BUT THESE RECORDS WERE
01:22PM 11 CREATED AND MAINTAINED AS PART OF THERANOS'S CLIA
01:22PM 12 LABORATORY.

01:22PM 13 SO THEY WEREN'T IN THE FORMAT THAT THE FDA WOULD EXPECT TO
01:22PM 14 SEE IF IT WALKED INTO A PURE DEVICE MANUFACTURER AND SAID SHOW
01:22PM 15 US YOUR QSR, YOUR DESIGN STUDY, SHOW US YOUR PROCEDURE FOR
01:22PM 16 DEALING WITH MEDICAL COMPLAINTS. THERANOS DID NOT HAVE
01:22PM 17 EVERYTHING SORT OF LAID OUT IN THE QSR FORMAT. AND THE FDA, AS
01:22PM 18 SEEN IN THE INSPECTION REQUEST FORM, UNDERSTOOD THAT THAT MIGHT
01:22PM 19 BE THE CASE.

01:22PM 20 NOW, THERANOS EXPLAINED THIS TO THE FDA DURING THE
01:22PM 21 INSPECTION AND IN CORRESPONDENCE AFTER THE INSPECTION. AND YOU
01:22PM 22 CAN FIND SOME OF THAT KEY CORRESPONDENCE SETTING FORTH THIS
01:22PM 23 POSITION AT DEFENSE EXHIBIT 50, AND THAT'S AT ECF 586-4.

01:23PM 24 AND WHEN I SAY "DEFENSE EXHIBIT," I MEAN THIS IS AN
01:23PM 25 EXHIBIT TO THE DEFENSE MOTION IN LIMINE TO EXCLUDE THIS

01:23PM 1 EVIDENCE. IT'S ACTUALLY AN EXEMPLAR GOVERNMENT PROPOSED TRIAL
01:23PM 2 EXHIBIT THAT WE WOULD BE MOVING TO EXCLUDE.

01:23PM 3 SO WE DON'T NEED TO PULL THIS ONE UP AND WALK THROUGH IT,
01:23PM 4 BUT I WILL JUST SAY BRIEFLY, THAT IT IS AN EMAIL FROM AN
01:23PM 5 INSPECTOR MARY HOLE, WHO IS FDA EMPLOYEE, ATTACHING VARIOUS
01:23PM 6 THERANOS SUBMISSIONS, INCLUDING A LETTER FROM THERANOS GENERAL
01:23PM 7 COUNSEL, HEATHER KING, THAT WAS SENT DURING THE INSPECTION THAT
01:23PM 8 KIND OF LAYS OUT THE BACKGROUND THAT I JUST WALKED THROUGH JUST
01:23PM 9 NOW.

01:23PM 10 SO THE FDA'S RESPONSE WAS, AND I'M PARAPHRASING HERE, BUT
01:23PM 11 WE FIND THE CTN'S ARE ACTUALLY A CLASS 2 MEDICAL DEVICE. WE
01:23PM 12 ARE MAKING A DETERMINATION THAT WE DISAGREE WITH YOU THAT
01:23PM 13 THEY'RE NOT AN LDT, AND YOU SHOULD HAVE BEEN ADHERING TO THE
01:23PM 14 QSR'S ALL ALONG. SO WE'RE GOING TO CITE YOU FOR YOUR FAILURE
01:24PM 15 TO DO SO.

01:24PM 16 THEY DID THIS PRINCIPALLY WITHOUT CONSIDERING WHAT
01:24PM 17 THERANOS HAD DONE IN THE CLIA LAB BECAUSE IT JUST DOESN'T
01:24PM 18 TRANSLATE OVER.

01:24PM 19 SO YOU CAN SEE HOW THIS HAPPENED, AND THIS IS AN EXAMPLE
01:24PM 20 AT DEFENSE EXHIBIT 52, ECF 586-6. AND AT ECF PAGE 4 OF THAT
01:24PM 21 EXHIBIT THERE'S A STATEMENT FROM AN -- IN AN EMAIL FROM
01:24PM 22 SEEMA SINGH, ANOTHER FDA INSPECTOR, WHO IS REPORTING TO HER
01:24PM 23 COLLEAGUES THAT THERANOS IS TELLING HER THAT THEY VALIDATE
01:24PM 24 THEIR TESTS IN THE CLIA LAB, BUT SHE REPORTS, I HAVE NOT LOOKED
01:24PM 25 AT ANY CLIA PERFORMANCE VALUATIONS.

01:24PM 1 SO THIS IS THE CONTEXT OF WHAT MAKES THE GOVERNMENT'S
01:24PM 2 PROPOSED USE OF THE EVIDENCE PROBLEMATIC HERE.

01:24PM 3 SO LET'S TAKE, FOR EXAMPLE, THE GOVERNMENT'S FAVORITE
01:24PM 4 OBSERVATION IN THE FORM 438 FOR THE PALO ALTO FACILITY. SO
01:24PM 5 THERE WERE ACTUALLY TWO INSPECTIONS HERE IN NORTHERN
01:25PM 6 CALIFORNIA. THERE WAS ONE AT THE PALO ALTO HEADQUARTERS,
01:25PM 7 BECAUSE THAT'S WHERE THE DESIGN -- SOME OF THE DESIGN
01:25PM 8 DOCUMENTATION WAS HELD, AND THEN THERE WAS ONE ACROSS THE BAY
01:25PM 9 IN NEWARK WHERE THE ACTUAL CTN'S WERE MANUFACTURED.

01:25PM 10 MS. SAHARIA, IF YOU COULD PULL UP GOVERNMENT'S EXHIBIT 14,
01:25PM 11 ECF 680, AND THIS IS AT PAGE 16.

01:25PM 12 SO WHILE SHE PULLS THIS UP, I'LL GIVE A LITTLE PRIMER ON
01:25PM 13 WHAT THIS OBSERVATION IS. THE FDA WENT IN AND SAID WE WANT TO
01:25PM 14 SEE YOUR DESIGN AND VALIDATION DOCUMENTATION THAT YOU WOULD BE
01:25PM 15 MAINTAINING AS A DEVICE MANUFACTURER.

01:25PM 16 AND THERANOS GIVES THEM A REPORT, AND THE FDA MAKES AN
01:25PM 17 OBSERVATION AND IT SAYS IT LOOKS LIKE THE REPORT HAS FLAGGED A
01:25PM 18 FEW ASSAYS FOR FURTHER STUDY, BUT THE REPORT WAS NOT
01:26PM 19 SUBSEQUENTLY UPDATED TO REFLECT THAT ADDITIONAL WORK HAD BEEN
01:26PM 20 DONE, AND SO THAT'S THE GENESIS OF THE CITATION. IT'S
01:26PM 21 INADEQUATE DESIGN, VALIDATION DOCUMENTATION AS A MANUFACTURER
01:26PM 22 OF A MEDICAL DEVICE.

01:26PM 23 SO THERANOS DID PROVIDE NARRATIVE EXPLANATIONS AND DATA
01:26PM 24 FROM IT'S CLIA LAB TO SHOW, OKAY, WE MIGHT NOT HAVE GONE BACK
01:26PM 25 AND UPDATED THIS MANUFACTURING PAPERWORK, BUT WE HAVE DONE

01:26PM 1 FURTHER STUDIES ON THE PERFORMANCE OF THE CTN'S. IN FACT, THEY
01:26PM 2 HAD DONE -- ALREADY AT THAT POINT THEY HAD DONE A 510(K)
01:26PM 3 SUBMISSION TO THE FDA FOR CLEARANCE OF THE ASSAYS, AND THEY
01:26PM 4 WERE ABOUT TO SUBMIT ANOTHER ONE.

01:26PM 5 WE JUST LOOKED AT SOME OF THOSE DOCUMENTS TOGETHER. SO
01:26PM 6 THOSE ARE THE DEFENSE EXHIBITS THAT I JUST WENT THROUGH. I
01:26PM 7 DIDN'T PULL THEM UP, BUT THEY'RE ATTACHED TO OUR MOTION.

01:26PM 8 AND ULTIMATELY THE FDA'S POSITION IS THAT'S OF NO USE.
01:26PM 9 YOU NEED TO BE COMPILING THESE QSR'S, COMPLYING WITH THIS,
01:27PM 10 YOU'RE A MEDICAL DEVICE MANUFACTURER, WE'RE GOING TO WRITE YOU
01:27PM 11 UP.

01:27PM 12 THE GOVERNMENT WANTS TO IGNORE THIS CONTEXT. IT WANTS TO
01:27PM 13 PUT THIS OBSERVATION BEFORE THE JURY, AND IT WANTS TO SAY THAT
01:27PM 14 THIS QSR VIOLATION MEANS THAT THERANOS, THAT TESTS RUN ON BLOOD
01:27PM 15 COLLECTED IN THE CTN'S WERE NOT CAPABLE OF PRODUCING ACCURATE
01:27PM 16 AND RELIABLE RESULTS.

01:27PM 17 THAT TYPE OF DETERMINATION WAS OUTSIDE THE SCOPE OF THIS
01:27PM 18 INSPECTION BY DEFINITION FOR ALL OF THE REASONS WE JUST
01:27PM 19 DISCUSSED.

01:27PM 20 THE SECOND BIG ISSUE WITH THE GOVERNMENT'S PROPOSED USE OF
01:27PM 21 THESE OBSERVATIONS IS THAT THEY'RE HYPER TECHNICAL. THIS IS,
01:27PM 22 IN THE FORM 438, THIS IS KIND OF ALL OF THE ELABORATION THAT
01:27PM 23 THEY GET. SO IN ITS OPPOSITION BRIEF THE GOVERNMENT QUOTES
01:28PM 24 THIS AND IT KINDS OF HOLDS IT OUT AS SELF-EVIDENT EVIDENCE OF
01:28PM 25 INACCURACY AND UNRELIABILITY.

01:28PM 1 THE GOVERNMENT HASN'T DISCLOSED AN EXPERT TO KIND OF
01:28PM 2 EXPLAIN WHAT IS THE CONNECTION BETWEEN DESIGN VALIDATION
01:28PM 3 MANUFACTURING DOCUMENTATION AND PERFORMANCE OF TESTS RUN ON
01:28PM 4 BLOOD COLLECTED IN THE CTN'S, OR TO EXPLAIN, OKAY, WHAT DOES
01:28PM 5 THIS CITATION MEAN WHEN APPLIED TO A COMPANY LIKE THERANOS THAT
01:28PM 6 IS ALSO ADHERING TO CLIA REGULATIONS?

01:28PM 7 FOR THESE FORM 438'S AND THE OTHER INSPECTION EVIDENCE, IT
01:28PM 8 SEEMS THAT THE GOVERNMENT'S POSITION IS THAT THE JURY COULD
01:28PM 9 JUST FIGURE IT OUT FOR THEMSELVES.

01:28PM 10 BUT WE SUBMIT THAT THAT'S NOT HELPFUL, AND THIS INSPECTION
01:28PM 11 EVIDENCE IS NOT RELEVANT, AND IT POSES A GRAVE DANGER OF JURY
01:28PM 12 CONFUSION AND UNFAIR PREJUDICE.

01:28PM 13 NOW, IT'S NO ANSWER TO SAY, WELL, THIS JUST GOES TO THE
01:29PM 14 WEIGHT. CAN'T YOU POINT THIS OUT TO THE JURY ON
01:29PM 15 CROSS-EXAMINATION? BUT, OF COURSE, THE DEFENSE CAN DO
01:29PM 16 CROSS-EXAMINATION, BUT IT'S NOT THE ROLE OF CROSS-EXAMINATION
01:29PM 17 TO HAVE TO SPEND LIKE MULTIPLE COURT DAYS EXPLAINING TO THE
01:29PM 18 JURY THAT THE EVIDENCE IS NOT WHAT THE GOVERNMENT REPRESENTS IT
01:29PM 19 TO BE IN A FUNDAMENTAL WAY.

01:29PM 20 THAT'S REALLY WHERE THE COURT SHOULD STEP IN. IT SHOULD
01:29PM 21 SAVE US ALL OF THE TIME AND EFFORT ON THIS BECAUSE IT WOULD BE
01:29PM 22 A LOT OF TIME AND EFFORT. THE DEFENSE WOULD HAVE TO CONSIDER
01:29PM 23 ASKING, LOOKING FOR AND RETAINING AN EXPERT TO EXPLAIN THESE
01:29PM 24 REGULATIONS. WE WOULD NEED SOMEBODY TO LOOK AT THE DESIGN
01:29PM 25 STUDY AND TO REBUT KIND OF THE OBSERVATION HERE, WHICH IS THAT

01:29PM 1 IT'S NOT ADEQUATELY DOCUMENTED.

01:29PM 2 WELL, WHAT DOES THAT MEAN? WHAT DOES THAT MEAN FOR THE
01:29PM 3 PERFORMANCE OF THE TEST?

01:29PM 4 BUT EVEN IF WE DID ALL OF THAT, THE JURY HAVING SAT
01:29PM 5 THROUGH IT, COULDN'T BE BLAMED FOR THINKING, WELL, MAYBE THERE
01:29PM 6 IS SOMETHING THERE. BUT WE SUBMIT THAT THERE REALLY IS NOT.

01:29PM 7 SO THAT'S THE CRUX OF OUR MOTION TO EXCLUDE THE FDA
01:29PM 8 INSPECTION EVIDENCE.

01:30PM 9 AND I THINK UNLIKE THE CMS INSPECTION WHICH ACTUALLY WENT
01:30PM 10 INTO THE CLIA LAB AND WAS LOOKING AT SOME INPUT INTO ITS
01:30PM 11 PERFORMANCE, QC PT, THIS IS KIND OF REALLY QUITE A SIDE SHOW,
01:30PM 12 AND IT'S A COMPLEX ONE. THERE'S A WHOLE OTHER SET OF
01:30PM 13 REGULATIONS THAT OTHERWISE WOULDN'T BE AT ISSUE IN THE CASE.

01:30PM 14 THE GOVERNMENT HAS PROPOSED TO USE SOME OF THE LEGAL
01:30PM 15 OBJECTIONS THAT THERANOS'S ATTORNEYS HAVE MADE TO THE
01:30PM 16 JURISDICTION TO THE FDA AS EVIDENCE OF, YOU KNOW, THE COMPANY
01:30PM 17 BEING UNCOOPERATIVE OR OTHERWISE UNHELPFUL WITH THE REGULATORS.

01:30PM 18 WE WOULD HAVE TO GO INTO WHETHER OR NOT THOSE OBJECTIONS
01:30PM 19 WERE LEGITIMATE, AND, YOU KNOW, AS WE JUST WALKED THROUGH, THIS
01:30PM 20 IS A COMPLEX AREA. IT'S ONE WHERE THE AGENCY'S POSITIONS WERE
01:30PM 21 EVOLVING DURING THE TIME THAT THERANOS WAS IN OPERATION.

01:30PM 22 SO THE FDA AT THE TIME DURING THE OBAMA ADMINISTRATION HAD
01:30PM 23 BEEN PROPOSING A CHANGE ON HOW IT WOULD REGULATE TESTS LIKE
01:31PM 24 THIS, EVENTUALLY ISSUED SOME UNBINDING GUIDANCE THAT HAS SINCE
01:31PM 25 BEEN EITHER RESCINDED OR -- I DON'T KNOW WHAT THE STATUS OF IT

01:31PM 1 IS, BUT IT ACTUALLY DIDN'T GO THROUGH.

01:31PM 2 SO, YOUR HONOR, WE SUBMIT THAT THIS EVIDENCE, IT REALLY
01:31PM 3 IS -- IT'S NOT PROBATIVE OF ANY MATERIAL POINT IN THE CASE AND
01:31PM 4 IT SHOULD BE EXCLUDED.

01:31PM 5 THE COURT: ALL RIGHT.

01:31PM 6 MR. LOOBY: YOUR HONOR, ON THE HEARSAY POINT, AND
01:31PM 7 I'D JUST LIKE TO MAKE A COUPLE OF QUICK POINTS. WE WON'T GO
01:31PM 8 INTO THE LAW BECAUSE THE ARGUMENTS ARE BASICALLY THE SAME.

01:31PM 9 BUT IN CERTAIN WAYS THE FORM 483'S, THEY FARE EVEN WORSE
01:31PM 10 UNDER THE RUBRIC THAT WE DISCUSSED. FIRST, THEY CONTAIN PURE
01:31PM 11 LEGAL CONCLUSIONS. THEY ACTUALLY DON'T EVEN REALLY CONTAIN
01:31PM 12 THAT MANY WHAT YOU COULD CALL FACTS.

01:31PM 13 THEN SECOND, THE GOVERNMENT HAS KIND OF ATTACHED TO ITS
01:31PM 14 OPPOSITION TO OUR MOTION IN LIMINE TWO EXHIBITS THAT ARE, YOU
01:32PM 15 KNOW, MULTIPAGE DOCUMENTS. ONE OF THEM IS 77 PAGES LONG, AND
01:32PM 16 THAT'S GOVERNMENT EXHIBIT 14 AT ECF 680, AND THEN THERE'S
01:32PM 17 GOVERNMENT EXHIBIT 15, ECF 680-1. THAT ONE IS 49 PAGES LONG.

01:32PM 18 AND THEY SEEM TO BE JUST COMPENDIUMS OF NARRATIVE
01:32PM 19 DOCUMENTS FROM THE INSPECTORS WHO WERE COUNTING ON A DAY-BY-DAY
01:32PM 20 BASIS WHAT THEY FOUND, WHO THEY TALKED TO, WHAT THERANOS
01:32PM 21 EMPLOYEES TOLD THEM. UNLIKE THE CMS REPORT, THEY ARE GIVEN
01:32PM 22 NAMES.

01:32PM 23 SO WE KNOW THAT A LOT OF THE INFORMATION DID NOT COME FROM
01:32PM 24 MS. HOLMES, BUT IT CAME FROM THE PEOPLE INVOLVED IN THE DESIGN
01:32PM 25 AND MANUFACTURING WHOM THE FDA INSPECTORS WERE QUERYING.

01:32PM 1 IT'S UNCLEAR WHAT THE GOVERNMENT IS ATTEMPTING TO DO, IF
01:32PM 2 IT'S GOING TO OFFER MORE OF THESE LONG FORM NARRATIVE ACCOUNTS
01:32PM 3 OF THE INSPECTION. THINK OF THEM KIND OF LIKE THE BACKUP
01:33PM 4 DOCUMENTS TO THIS KIND OF THE TOP LEVEL CONCLUSION.

01:33PM 5 THEY WERE NOT ON THE GOVERNMENT'S EXHIBIT LIST. BUT NOW
01:33PM 6 THE GOVERNMENT HAS KIND OF COME AND PUT THEM IN THE OPPOSITION,
01:33PM 7 AND IT'S TAKEN THE POSITION IN THE OPPOSITION THAT THIS IS KEY
01:33PM 8 EVIDENCE IN THE CASE.

01:33PM 9 SO THERE'S A LOT OF HEARSAY. THERE'S MULTIPLE LEVELS OF
01:33PM 10 HEARSAY PROBLEMS IN THOSE DOCUMENTS, AND WE SUBMIT THAT THEY
01:33PM 11 WOULD -- THEY SHOULD NOT BE ADMITTED.

01:33PM 12 I THINK THAT'S IT FROM THE HEARSAY POINT. BEFORE I EITHER
01:33PM 13 TAKE QUESTIONS FROM YOUR HONOR OR RESERVE MY TIME FOR REBUTTAL,
01:33PM 14 THERE'S JUST A FEW WORDS ABOUT SOME OF THE SUPERFLUOUS EVIDENCE
01:33PM 15 THAT THE GOVERNMENT PUTS IN ITS OPPOSITION. THESE INCLUDE LIKE
01:33PM 16 A LONG EXCERPT OF TEXT MESSAGES ALLEGEDLY SENT BETWEEN
01:33PM 17 MS. HOLMES AND MR. BALWANI DURING THE INSPECTION. THEY ALSO
01:33PM 18 INCLUDE CHARACTERIZATIONS ABOUT THE PROPRIETARY OF THE LAWYER'S
01:33PM 19 CONDUCT AND OTHER CONDUCT DURING -- IN OBJECTING TO THE FDA AT
01:33PM 20 CERTAIN POINTS IN TIME.

01:33PM 21 ALTHOUGH I WILL NOTE THAT THERE WAS NEVER ACCESS DENIED TO
01:33PM 22 THE FDA TO DO AN INSPECTION. THERE WERE OBJECTIONS TO THE
01:34PM 23 RECORD ESSENTIALLY AND OTHER COMPANY DOCUMENTS THAT ARE
01:34PM 24 RELATING TO THE CTN'S BUT ARE UNRELATED TO AND PREDATE THE FDA
01:34PM 25 INSPECTION.

01:34PM 1 SO I WOULD SUBMIT, YOUR HONOR, THAT THIS IS ALL JUST NOISE
01:34PM 2 TO DISTRACT FROM THE FACT THAT THE FDA INSPECTION DOES NOT BEAR
01:34PM 3 ON THE GOVERNMENT'S ACCURACY AND RELIABILITY CASE.

01:34PM 4 THE FDA INSPECTION -- AND THIS IS, KIND OF GOING BACK TO
01:34PM 5 THE 403 AND THE WASTE OF TIME ISSUES, THIS IS ALL THE STUFF
01:34PM 6 THAT COULD GET SWEEPED IN IF WE ARE PERMITTED -- IF WE HAVE TO GO
01:34PM 7 DOWN THIS ROAD IN ADDRESSING WHAT HAPPENED IN AUGUST AND
01:34PM 8 SEPTEMBER OF 2015.

01:34PM 9 SO WITH THAT, YOUR HONOR.

01:34PM 10 THE COURT: OKAY. THANK YOU VERY MUCH. THANK YOU.
01:34PM 11 MR. LEACH.

01:34PM 12 MR. LEACH: THANK YOU, YOUR HONOR. GOOD AFTERNOON.

01:35PM 13 THE DEFENDANT'S PROPOSED ORDER SEEKS TO EXCLUDE ANY
01:35PM 14 EVIDENCE, ARGUMENT, OR REFERENCE TO THE FDA'S 2015 INSPECTION.

01:35PM 15 THERE'S BEEN A LOT OF FOCUS ON THE FORM 483'S FROM THE
01:35PM 16 NEWARK AND THE PALO ALTO LABS, BUT THEIR PROPOSED ORDER WANTS
01:35PM 17 NO MENTION THAT THE FDA CAME TO INSPECT THERANOS IN SEPTEMBER
01:35PM 18 OF 2015.

01:35PM 19 THE COURT SHOULD DECLINE TO ISSUE SUCH A SWEEPING ORDER.
01:35PM 20 THE RELEVANCE OF THIS EVIDENCE IS SIMPLE AND MANIFEST.

01:35PM 21 IN SEPTEMBER OF 2015 THE FDA, ONE OF THERANOS'S PRIMARY
01:35PM 22 REGULATORS, CAME FOR AN INSPECTION TO LOOK AT SOME OF
01:35PM 23 THERANOS'S TECHNOLOGY, THE CTN, AND TO USE A VERY NON-LEGAL
01:35PM 24 TERM, THE DEFENDANT FREAKED OUT ABOUT IT.

01:35PM 25 WE KNOW THAT FROM THE TEXT SHE SUBMITS TO MR. BALWANI WHEN

01:36PM 1 THE INSPECTORS COME. THEY INSIST THAT EVERYTHING BE STAMPED
01:36PM 2 "CONFIDENTIAL." THEY SAY WE'RE GOING TO RUN CIRCLES AROUND THE
01:36PM 3 FDA. THEY SAY WE HAVE TO FIX REPRESENTATIONS ON OUR WEBSITE
01:36PM 4 BECAUSE WE MIGHT BE MARKETING THESE LDT'S BECAUSE OF THE CTN'S.

01:36PM 5 THEY TALK ABOUT STOP MAKING THE CTN'S ALTOGETHER. THEY
01:36PM 6 TALK ABOUT HOW THEY NEED TO FIX THE CTN'S, THERANOS'S
01:36PM 7 TECHNOLOGY.

01:36PM 8 NONE OF THIS IS THE BEHAVIOR OF SOMEBODY WHO BELIEVES IN
01:36PM 9 THEIR TECHNOLOGY. NONE OF THIS IS THE BEHAVIOR OF SOMEBODY WHO
01:36PM 10 THINKS THEIR, THAT THEIR -- THAT THE THERANOS TECHNOLOGY IS
01:36PM 11 ACCURATE AND RELIABLE.

01:36PM 12 IF THERE WERE NO PROBLEMS, INSTEAD OF HIRING THE FORMER,
01:36PM 13 YOU KNOW, A FORMER HIGH LEVEL FDA OFFICIAL WHO IS NOW AT
01:36PM 14 BOIES SCHILLER TO COME DEFEND THIS INSPECTION, MS. HOLMES WOULD
01:36PM 15 HAVE SAID COME IN, COME AND SEE EVERYTHING, HERE'S THE CTN'S,
01:37PM 16 HERE'S OUR REPORTS, WE'RE AN OPEN BOOK.

01:37PM 17 THAT'S NOT WHAT HAPPENED HERE. THERE WERE OBJECTIONS.
01:37PM 18 THERE WERE CONTENTIOUS BACK AND FORTH BETWEEN THE FDA
01:37PM 19 INSPECTORS, AND THE TEXT MESSAGES REVEAL DEEP, DEEP ANXIETY
01:37PM 20 ABOUT WHAT THEY'RE GOING TO FIND FOR WHATEVER REASON THAT
01:37PM 21 THEY'RE THERE. THE REASON IS ALMOST IRRELEVANT.

01:37PM 22 IT'S THE FACT THAT THEY ARE REACTING THIS WAY TO A
01:37PM 23 GOVERNMENT INSPECTION THAT REFLECTS INTENT AND KNOWLEDGE THAT
01:37PM 24 THEIR TECHNOLOGY ISN'T UP TO SNUFF.

01:37PM 25 THE COURT: SO, MR. LEACH, IS THAT -- ARE THOSE THE

01:37PM 1 FACTS THAT YOU WOULD SEEK TO INTRODUCE, THAT IS, THE CONDUCT OF
01:37PM 2 THE PARTIES, MS. HOLMES AND OTHERS, IN REGARDS TO A SEARCH AND
01:37PM 3 INVESTIGATION BY THE FDA? IS IT JUST THE CONDUCT THAT IS
01:37PM 4 PARAMOUNT HERE WITHOUT THE REPORT?

01:37PM 5 MR. LEACH: THAT'S PRIMARILY WHAT I'M INTERESTED,
01:37PM 6 YOUR HONOR. AND THE PURPOSE OF ATTACHING SOME OF THESE LENGTHY
01:37PM 7 DESCRIPTIONS OF WHAT HAPPENED DURING THE FDA INSPECTION IS TO
01:38PM 8 GIVE CONTEXT THAT EITHER HEATHER KING OR AN FDA WITNESS, IF
01:38PM 9 NECESSARY, COULD SAY MS. HOLMES SAID X DURING THE FDA
01:38PM 10 INSPECTION. MS. HOLMES WAS VERY INVOLVED IN THE FDA
01:38PM 11 INSPECTION. SHE SAID WE'RE ALL USING THESE CTN'S FOR
01:38PM 12 12 PERCENT OF OUR TESTS, SO YOU DON'T NEED TO BE CONCERNED
01:38PM 13 HERE. SO IT IS PRIMARILY FOR THAT REACTION.

01:38PM 14 WE DO -- I DO CARE ABOUT THE 483, AND I'M NOT GOING TO
01:38PM 15 REARGUE THE HEARSAY ISSUE, BUT I THINK THAT THEY'RE TRYING TO
01:38PM 16 MAKE SOMETHING THAT -- A LOT MORE COMPLICATED THAN IT IS,
01:38PM 17 YOUR HONOR. AND IF WE NEED TO NOTICE AN FDA WITNESS, AN EXPERT
01:38PM 18 TO EXPLAIN WHAT SHE WROTE ON THE FORM, WE CAN DO THAT.

01:38PM 19 BUT IT GOES TO NOTICE. IT GOES TO THE INADEQUACY OF THE
01:38PM 20 TESTING FOR THOSE PARTICULAR FOUR ASSAYS. THE THRUST OF WHAT
01:39PM 21 THAT FORM IS, IS THAT THEY HAD A PLAN, THEY SENT OUT THE
01:39PM 22 ACCEPTANCE CRITERIA THAT THESE ASSAYS NEED TO MEET, AND THEY
01:39PM 23 DIDN'T MEET THEM.

01:39PM 24 AND WHAT DID THEY DO? THEY KEPT TESTING.

01:39PM 25 NOW, THERANOS INSISTS THAT THEY HAVE SOME DOCUMENTS TO

01:39PM 1 BACK THAT UP, BUT THE FDA WASN'T ACCEPTING THAT. AND WE THINK
01:39PM 2 THOSE FACTS ARE PROBATIVE OF THE ACCURACY AND RELIABILITY OF
01:39PM 3 THE TESTS.

01:39PM 4 SO I DO CARE ABOUT THE 483, AND I THINK IT'S RELEVANT, AND
01:39PM 5 THIS IS NOT THE MASSIVE MINI TRIAL THAT IT IS MADE OUT TO BE,
01:39PM 6 BUT AN ORDER THAT EXCLUDES ALL FDA INSPECTION EVIDENCE IS WAY
01:39PM 7 TOO BROAD.

01:39PM 8 SHE MAKES MANY STATEMENTS DURING THIS TIME PERIOD THAT ARE
01:39PM 9 REFLECTIVE OF HER INTENT, HER CONTROL OF THE LAB, OVER HER
01:39PM 10 KNOWLEDGE OF THE TECHNOLOGY, AND, FRANKLY, HER ANXIETY ABOUT
01:39PM 11 WHAT THEY WERE GOING TO FIND AND WHAT THEY WERE GOING TO DO.

01:39PM 12 THE COURT: THANK YOU. SO THIS WOULD COME IN AS A
01:39PM 13 FOUNDATIONAL, THERE WOULD BE EVIDENCE OF THIS INSPECTION, THIS
01:40PM 14 FDA 2015 INSPECTION, AND THEN YOU SEEK TO GET IN MS. HOLMES'S
01:40PM 15 AND OTHERS' REACTIONS TO IT, ON DAY ONE AT HOUR TWO THIS IS
01:40PM 16 WHAT WAS SAID BY HER, THAT COMES IN AS AN ADMISSION OR FOR SOME
01:40PM 17 OTHER REASON?

01:40PM 18 MR. LEACH: YES.

01:40PM 19 THE COURT: AND THEN THE CONDUCT WAS THIS, AND THEN
01:40PM 20 THIS, AND THIS, AND THIS?

01:40PM 21 MR. LEACH: YES.

01:40PM 22 THE COURT: WITHOUT NECESSARILY -- I'M NOT ASKING
01:40PM 23 YOU TO CONCEDE WHETHER OR NOT YOU'LL WANT THE DOCUMENT IN, BUT
01:40PM 24 IT SOUNDS LIKE IT'S REALLY THE CONDUCT OF THE PARTIES IN
01:40PM 25 RELATION TO THE INSPECTION THAT IS TELLING.

01:40PM 1 MR. LEACH: YES, YOUR HONOR.

01:40PM 2 NOW, I AM WORRIED ABOUT IF FOR WHATEVER REASON THE FORM
01:40PM 3 483 IS NOT PERMITTED, I AM WORRIED ABOUT THE MISPERCEPTION
01:40PM 4 ABOUT THE RELATIONSHIPS BETWEEN THE FDA AND THERANOS WERE
01:40PM 5 WONDERFUL AND HAPPY AND EVERYTHING WAS FINE. SHE DOES MAKE
01:41PM 6 SOME STATEMENTS ABOUT THE FDA AFTERWARDS.

01:41PM 7 BUT THE CRUX OF THE GOVERNMENT'S RELEVANCE AND 403
01:41PM 8 ARGUMENTS ARE HER REACTION TO THIS INSPECTION IS DEEPLY
01:41PM 9 RELEVANT. A SWEEPING ORDER THAT EVERYTHING IS OUT IS NOT
01:41PM 10 APPROPRIATE. I WOULD URGE THE COURT TO WAIT TO SEE IF WE
01:41PM 11 ACTUALLY OFFER THE 483 AS OPPOSED TO THE OTHER DOCUMENTS.

01:41PM 12 BUT THE SWEEPING ORDER THAT THEY'RE ASKING FOR IS JUST NOT
01:41PM 13 WARRANTED.

01:41PM 14 THE COURT: SO I ASKED MR. LOOBY A QUESTION ABOUT
01:41PM 15 THE TIMING OF THIS INSPECTION AND WHETHER IT WAS A REQUEST OR A
01:41PM 16 VOLUNTARY. AND I THINK HE SAID NO, IT WAS NOT. I THINK THAT'S
01:41PM 17 WHAT HE SAID.

01:41PM 18 I WAS CURIOUS, IT LOOKS LIKE DIDN'T THERANOS, AND
01:41PM 19 MR. LOOBY WILL SHARE HIS OPINION, DIDN'T THEY SEEK APPROVAL
01:41PM 20 FROM THE FDA IN 2013 AND THEN THERE WAS -- BETWEEN 2013 AND
01:41PM 21 2015 OBVIOUSLY THERE WERE, I PRESUME, SOME CONVERSATIONS, AND
01:42PM 22 THEN ULTIMATELY UNANNOUNCED THE FDA SHOWS UP TO DO THE
01:42PM 23 INSPECTION FOR THAT REQUEST I SUPPOSE FOR CERTIFICATION.

01:42PM 24 IS THAT THE EVENT HERE?

01:42PM 25 MR. LEACH: THAT IS LARGELY CORRECT, YOUR HONOR.

01:42PM 1 I -- THAT IS CORRECT.

01:42PM 2 THE COURT: FEEL FREE TO CORRECT ME.

01:42PM 3 MR. LEACH: WELL, I'M TRYING TO THINK IF THERE'S A
01:42PM 4 NUANCE TO IT THAT I DISAGREE WITH AND OFF THE FLY I DON'T.

01:42PM 5 THERE WAS DIALOGUE BETWEEN THERANOS AND THE FDA THROUGHOUT
01:42PM 6 2013 AND 2014.

01:42PM 7 THE 2015 INSPECTION IS UNANNOUNCED. THEY SHOW UP ON
01:42PM 8 THERANOS'S DOOR. I CAN'T SAY SIMPLY THROUGH LACK OF
01:42PM 9 PREPARATION, YOU KNOW, EXACTLY WHO WITHIN THE FDA MADE THE
01:42PM 10 DECISION TO SHOW UP THERE, BUT IT WAS UNANNOUNCED, IT WAS --
01:42PM 11 THEY DIDN'T TELL -- THE FDA DIDN'T TELL THERANOS THEY WERE
01:43PM 12 COMING.

01:43PM 13 WE DID SEE FROM THE DOCUMENT MR. LOOBY JUST SHOWED, THIS
01:43PM 14 IS EXHIBIT 82 AT 6, THAT PART OF THE REASON THE FDA WAS THERE
01:43PM 15 WAS BECAUSE PRE-SUBMISSIONS THAT THERANOS HAD SUBMITTED RAISED
01:43PM 16 SERIOUS CONCERNS ABOUT THE SAFETY AND THE EFFECTIVENESS OF THE
01:43PM 17 CTN DEVICES BECAUSE PRELIMINARY DATA REVIEWED BY THE FDA
01:43PM 18 DEMONSTRATE THAT THE RESULTS OF SAMPLES COLLECTED AND STORED IN
01:43PM 19 THE NANOTAINER WERE MUCH LESS ACCURATE.

01:43PM 20 SO I ANTICIPATE THERE WOULD BE SOME TESTIMONY OR REASONS
01:43PM 21 WHY THE FDA SHOWED UP. BUT IT WAS NOT, IT WAS NOT A -- IT WAS
01:43PM 22 COMPLETELY UNANNOUNCED. THEY WERE THERE IN BOTH LOCATIONS.

01:43PM 23 THE COURT: WAS IT -- MAYBE IT'S NOT IMPORTANT. I'M
01:43PM 24 JUST CURIOUS OF THE TIMELINE OF THIS.

01:43PM 25 WAS THEIR SHOWING UP THERE, IT SOUNDS LIKE IT WAS

01:43PM 1 CONNECTED TO THE ORIGINAL REQUEST TO APPROVE OUR DEVICE.

01:44PM 2 MR. LEACH: I GUESS THAT'S A FAIR INFERENCE,
01:44PM 3 YOUR HONOR.

01:44PM 4 THE COURT: AS OPPOSED TO JUST AN UNANNOUNCED
01:44PM 5 SPOT-CHECK. WHAT ARE YOU DOING HERE? WE'VE NEVER SEEN YOU
01:44PM 6 BEFORE. BUT THERE WAS SOME COMMUNICATION.

01:44PM 7 AND I GUESS, AND I DON'T KNOW IF THIS IS ACCURATE OR NOT,
01:44PM 8 BUT IS THAT -- MAYBE THIS MISPHRASES IT, BUT WAS THAT A
01:44PM 9 JUSTIFICATION FOR THE FDA BEING ON THE PROPERTY AT THAT TIME?

01:44PM 10 MR. LEACH: I THINK THAT'S A FAIR CHARACTERIZATION,
01:44PM 11 YOUR HONOR. I HAVEN'T REVIEWED THE FDA WITNESS STATEMENTS TO
01:44PM 12 ANSWER THAT WITH A LEVEL OF DEFINITIVENESS FOR YOUR HONOR, BUT
01:44PM 13 THERE HAD BEEN SOME ENGAGEMENT BETWEEN THE FDA. THERE WERE
01:44PM 14 SOME 510(K) SUBMISSIONS.

01:44PM 15 AND THE DOCUMENT WE JUST LOOKED AT REFLECTS THAT SOME OF
01:44PM 16 THE REASONS FOR THE EXAM WAS ANXIETY OVER THAT DATA.

01:44PM 17 THE COURT: FROM MS. HOLMES AND HER TEAM?

01:44PM 18 MR. LEACH: NO, FROM THE FDA.

01:44PM 19 THE COURT: FROM THE FDA. I SEE.

01:44PM 20 SO I GUESS YOU WOULDN'T CALL THEM INVITEES, BUT THEY WERE
01:44PM 21 THERE BECAUSE THERE WAS AN APPLICATION MADE FOR APPROVAL.

01:45PM 22 MR. LEACH: THERE WERE SOME APPLICATIONS FOR
01:45PM 23 APPROVAL. I THINK THE FDA'S CONCERN WAS THAT THEY WERE USING
01:45PM 24 THE NANOTAINER IN A WAY THAT WASN'T CONSISTENT WITH THEIR VIEW
01:45PM 25 OF THE LDT FRAMEWORK. SO IT WAS A CONCERN THAT THERANOS WAS

01:45PM 1 DOING SOMETHING WITHOUT APPROVAL.

01:45PM 2 BUT THERE CERTAINLY HAD BEEN SUBMISSIONS FOR APPROVAL BY
01:45PM 3 THERANOS TO CERTAIN ASPECTS OF THE TECHNOLOGY BEFORE.

01:45PM 4 THE COURT: OKAY. WHAT ABOUT MR. LOOBY TOLD US THAT
01:45PM 5 ALL OF THIS OCCURRED AFTER THE LAST ROUND OF INVESTOR --

01:45PM 6 MR. LEACH: I THINK THAT'S A RED HERRING,
01:45PM 7 YOUR HONOR.

01:45PM 8 I THINK STATEMENTS -- A DEFENDANT CAN MAKE STATEMENTS.
01:45PM 9 FIRST OF ALL, THE SCHEME ALLEGED IN THE INDICTMENT ON THE
01:45PM 10 INVESTOR COUNT GOES THROUGH 2015. SO THIS IS DURING THE TIME
01:45PM 11 PERIOD OF THE CONSPIRACY.

01:46PM 12 THE LAST ACTUAL MONEY THAT CAME IN THE DOOR WAS AT SOME
01:46PM 13 POINT EARLIER IN 2015, BUT WE'VE PRESENTED SOME EVIDENCE THAT
01:46PM 14 THEY WERE PURSUING PARTNERSHIPS THAT AT ONE POINT HAD AN EQUITY
01:46PM 15 COMPONENT LATE INTO 2015.

01:46PM 16 I DON'T THINK THERE WAS A MOMENT WHERE MS. HOLMES SAID I'M
01:46PM 17 DONE, DON'T NEED TO RAISE ANY MORE MONEY. SO I DON'T THINK
01:46PM 18 IT'S AS CLEAN OF A BREAK AS THEY SUGGEST IT IS.

01:46PM 19 BUT EVEN IF IT WAS AFTER THE FACT, YOUR HONOR, A, IT'S
01:46PM 20 CLOSE IN TIME; B, A DEFENDANT CAN MAKE STATEMENTS AFTER THE
01:46PM 21 SCHEME IS COMPLETED THAT REFLECTS ANXIETY ABOUT GETTING CAUGHT
01:46PM 22 OR AN INSPECTOR COMING IN AND SEEING THEIR TECHNOLOGY IS NOT
01:46PM 23 WHAT IT IS.

01:46PM 24 IT'S HER REACTION TO THIS FDA INSPECTION THAT, YOU KNOW,
01:46PM 25 WHENEVER IT IS, AND IT IS VERY CLOSE IN TIME. IT'S WHILE

01:46PM 1 MR. CARREYROU IS DOING SOME OF HIS RESEARCH AND IS DRAFTING THE
01:46PM 2 ARTICLE.

01:46PM 3 SO I DON'T THINK THERE IS SOME TEMPORAL CONNECTION THAT
01:47PM 4 MAKES THIS IRRELEVANT.

01:47PM 5 THE COURT: YOU KNOW, I SHOULD HAVE -- I DON'T MEAN
01:47PM 6 TO GO BACK TO OUR CONVERSATION BEFORE THE LUNCH BREAK BUT 572,
01:47PM 7 THIS COULD COME IN CONTEXT THERE AS WELL AS TO STATEMENTS
01:47PM 8 THAT -- I THINK THOSE WERE IN 2016. AND ARE THOSE OUTSIDE OF
01:47PM 9 THE CHARGING PERIOD SUCH THAT THEY LACK RELEVANCE?

01:47PM 10 MR. LEACH: NOT FOR THE PATIENT COUNT, YOUR HONOR,
01:47PM 11 NO. I DON'T HAVE THE INDICTMENT IN FRONT OF ME BUT SOME OF THE
01:47PM 12 ALLEGATIONS -- THE CONSPIRACY CONTINUES INTO 2016.

01:47PM 13 AGAIN, I'M NOT AWARE OF A RULE THAT SAYS ONLY STATEMENTS
01:47PM 14 DURING A SCHEME TO DEFRAUD ARE RELEVANT. IF MIRACULOUSLY
01:47PM 15 MS. HOLMES WERE TO MAKE A STATEMENT TODAY RELATING TO HER
01:47PM 16 INTENT, WE WOULDN'T CERTAINLY SAY THAT HER TESTIMONY BEFORE THE
01:47PM 17 S.E.C. WAS IRRELEVANT BECAUSE IT'S THREE YEARS LATER.

01:47PM 18 IT'S CLOSE IN TIME, AND IT'S WITHIN THE CONSPIRACY ALLEGED
01:47PM 19 IN THE PATIENT COUNT, AND IT'S SO CONNECTED TO EVENTS THAT
01:47PM 20 HAPPENED DURING THE SCHEME. I DON'T SEE SOME TEMPORAL ISSUE
01:48PM 21 THERE WITH ITS RELEVANCE.

01:48PM 22 THE COURT: OKAY. ALL RIGHT. THANK YOU.

01:48PM 23 MR. LEACH: THANK YOU, YOUR HONOR.

01:48PM 24 THE COURT: MR. LEACH, MAYBE YOU WANT TO STAND UP
01:48PM 25 THERE. I MIGHT ASK YOU TO COME BACK.

01:48PM 1 MR. LEACH: I'M HAPPY TO DO THAT, YOUR HONOR.

01:48PM 2 MR. LOOBY: THANK YOU, YOUR HONOR.

01:48PM 3 AND OUR ARGUMENT ISN'T THAT THERE IS LIKE A SHARP CUTOFF
01:48PM 4 DATE AFTER WHICH ALL STATEMENT, ALL EVIDENCE IN THE CASE WOULD
01:48PM 5 BE IRRELEVANT AFTER THE CLOSING OF THE LAST INVESTMENT ROUND.

01:48PM 6 WHAT WE'RE TALKING ABOUT IS THE WAY THAT THE GOVERNMENT
01:48PM 7 CHARGED THE CASE THE FDA IS GOING TO BE PART OF THE CASE.
01:48PM 8 THERE IS REPRESENTATION ABOUT THE FDA, ABOUT WHAT REQUIREMENTS
01:48PM 9 WERE APPROVED, WHAT APPROVALS OR CLEARANCES WERE REQUIRED OR
01:48PM 10 NOT.

01:48PM 11 AND AS THE INSPECTION REPORT SHOWED, AT THE TIME THAT THE
01:48PM 12 FDA WENT IN, I MEAN, THE FDA AND THERANOS WERE NO STRANGERS TO
01:48PM 13 ONE ANOTHER. THEY HAD BEEN DEALING EXTENSIVELY FOR MANY YEARS.
01:48PM 14 THERE HAVE BEEN MANY SUBMISSIONS ABOUT GETTING CLEARANCE FOR
01:49PM 15 ITS TESTS. THAT'S ALL GOING TO BE PART OF THE CASE
01:49PM 16 ESSENTIALLY. THAT'S PART OF THE -- IT ALL BEARS ON THE
01:49PM 17 INDICTMENT ALLEGATION.

01:49PM 18 WHAT THE INDICTMENT ALLEGATION DOESN'T RELATE TO IS THE
01:49PM 19 INSPECTION. AND WHAT I HEARD FROM MR. LEACH IS THAT THE
01:49PM 20 INSPECTION IS BASICALLY BEING BROUGHT IN ON THE BACK OF A
01:49PM 21 HANDFUL OF TEXT MESSAGES SENT DURING THE INSPECTION. AND SO I
01:49PM 22 THINK IF YOU LOOK AT THE GOVERNMENT'S OPPOSITION AT PAGE 674,
01:49PM 23 DOCUMENT 674 ON THE ECF, AND PAGE 5 TO 7, THESE ARE THE TEXT
01:49PM 24 MESSAGES THAT ARE NOW GOING TO BRING IN AN ENTIRE INSPECTION
01:49PM 25 AND FORM 483'S, AND MAYBE SOME NARRATIVE ACCOUNTS FROM

01:49PM 1 INSPECTORS, WE MIGHT GET A NEW GOVERNMENT WITNESS APPARENTLY
01:49PM 2 WHO HAS NOT BEEN DISCLOSED BECAUSE THE GOVERNMENT HASN'T PUT ON
01:49PM 3 ITS WITNESS LIST A SINGLE PERSON WHO WAS PRESENT FOR THE
01:49PM 4 INSPECTION AND STILL HAS NOT DONE THAT.

01:50PM 5 SO, YOU KNOW, YOUR HONOR, WE POINTED OUT IN OUR REPLY WHY
01:50PM 6 SOME OF THESE AND KIND OF CHERRY PICKED TEXT MESSAGES ARE BEING
01:50PM 7 TAKEN OUT OF CONTEXT.

01:50PM 8 AND, YOU KNOW, EVEN IF YOU WERE TO ACCEPT THE GOVERNMENT'S
01:50PM 9 READING, I DON'T THINK THAT THE FDA INSPECTION EVIDENCE AND THE
01:50PM 10 FACT OF THE INSPECTION OR THE FACT THAT THEY WERE OBSERVATIONS
01:50PM 11 THAT THERANOS WAS FOUND TO BE NONCOMPLIANT WITH THE FOOD, DRUG,
01:50PM 12 AND COSMETIC APP, THAT THOSE ARE NECESSARY TO PUT ANY OF THIS
01:50PM 13 IN CONTEXT. THIS SEEMS TO ME LIKE IT'S REALLY KIND OF PUTTING
01:50PM 14 THE HORSE BEFORE THE CART OR THE CART BEFORE THE HORSE. I AM
01:50PM 15 SORRY.

01:50PM 16 THE COURT: IT'S BEEN A LONG TIME SINCE WE'VE HAD
01:50PM 17 THOSE.

01:50PM 18 MR. LOOBY: YEAH.

01:50PM 19 THE COURT: WHAT I WAS CURIOUS ABOUT, WHAT MR. LEACH
01:50PM 20 AND I PROBED A LITTLE BIT ABOUT IS THAT YOU HEARD MR. LOOBY
01:50PM 21 TALK VERY ARTICULATEDLY ABOUT THIS FORM AND THE PROBLEMS WITH
01:50PM 22 THIS FORM AND THE ISSUES WITH THE FORM AND THE ISSUES PRESENTED
01:51PM 23 IN THE FORM. AND WHAT IS IT THAT YOU WANT IN?

01:51PM 24 IT SOUNDS LIKE WHAT THE GOVERNMENT SEEKS TO GAIN IS REALLY
01:51PM 25 THE CONDUCT OF THE PARTIES ONCE THE INSPECTORS ARE EITHER ON

01:51PM 1 SITE OR THEY HAVE GIVEN NOTICE THAT THEY'RE ON SITE AND WHAT
01:51PM 2 THEY'RE LOOKING FOR AND AS YOU REFERENCE THIS EXCHANGE OF TEXT
01:51PM 3 MESSAGES AND THE PARTIES, THE STATEMENTS.

01:51PM 4 IT'S NOT SO MUCH THE ACTUAL FORM, ALTHOUGH I'M SURE YOU
01:51PM 5 WOULD LIKE IT TO COME IN, BUT IT'S THE CONDUCT OF THE PARTIES
01:51PM 6 IN REGARDS TO -- THE FDA IS HERE AND WE THINK THAT THEY'RE
01:51PM 7 LOOKING AROUND AT OUR MACHINES. WHAT SHOULD WE DO? CIRCLE THE
01:51PM 8 WAGONS. DO THIS, DO THAT. THAT SEEMS TO BE -- IS THAT A
01:51PM 9 FAIR --

01:51PM 10 MR. LEACH: IT'S A VERY FAIR SUMMARY, YOUR HONOR.

01:51PM 11 MR. LOOBY: SO, YOUR HONOR, I THINK THE RELEVANCE OF
01:51PM 12 THAT TYPE OF EVIDENCE ACTUALLY -- IT RELIES ON THE FACT THAT
01:51PM 13 THE FDA INSPECTION, LIKE, HAS SOMETHING TO DO WITH THE
01:52PM 14 PERFORMANCE OF THE TEST AND THE RESULTS COMING OUT OF THE LAB.

01:52PM 15 THE COURT: SO I LOOK AT IT AS -- AND HELP ME WITH
01:52PM 16 THIS. THAT IS WHY I ASKED THE QUESTIONS ABOUT INITIALLY THAT
01:52PM 17 IT SEEMED LIKE IN THE COURSE OF BUSINESS THERANOS WAS SEEKING
01:52PM 18 TO GET LICENSURE OR APPROVAL OF THEIR MACHINE AND PART OF THAT
01:52PM 19 PROCESS IS NOW WE PROBABLY ARE ALL FAMILIAR WITH FDA APPROVAL.
01:52PM 20 WE HAD TO WAIT ANXIOUSLY WHILE THE FDA APPROVES CERTAIN
01:52PM 21 VACCINES THAT ALL OF US COULD GET.

01:52PM 22 SO I THINK THE PUBLIC HAS SOME GENERAL IDEA AT A HIGH
01:52PM 23 LEVEL ABOUT WHAT FDA APPROVAL IS. BUT IT SEEMS LIKE THAT'S
01:52PM 24 WHAT THIS WAS. THERANOS WANTED THIS TO MARKET WHEN ALBEIT IT
01:52PM 25 TOOK TWO YEARS TO GET THERE. IT IS THE GOVERNMENT AFTER ALL,

01:52PM 1 BUT IT TOOK A WHILE TO PROCESS ALL OF THAT.

01:52PM 2 BUT THEN THIS VISIT WAS OUT OF THE ORDINARY, I SUPPOSE, IN
01:52PM 3 THAT IT WAS UNANNOUNCED, BUT THEY CERTAINLY, AS PART OF THE
01:52PM 4 PROCESS, COULD BE THERE AND DO THIS AND DO THIS INSPECTION.

01:53PM 5 THE REASONS WERE, I THINK MR. LEACH SAYS, CONCERNS THAT
01:53PM 6 THEY HAD FOR WHATEVER THE SOURCE IS OF THAT AND WHETHER THAT
01:53PM 7 COMES IN AND HOW THAT COMES IN PERHAPS IS A DIFFERENT FUNCTION.

01:53PM 8 BUT THE GENESIS OF THEM BEING THERE IS TO LOOK AND INSPECT
01:53PM 9 THESE PARTICULAR MACHINES. SHOULD THAT COME IN WITH SOME
01:53PM 10 SANITIZATION? I HEAR WHAT YOU'RE SAYING. DON'T GET THE REPORT
01:53PM 11 IN BECAUSE IT SAYS ALL OF THIS BECAUSE WE DON'T WANT TO BURDEN
01:53PM 12 THE JURY WITH HAVING ANOTHER EXPERT TELL THEM WHAT THIS PAPER
01:53PM 13 SAYS. MAYBE NOT. BUT JUST THAT GENERAL CONCEPT.

01:53PM 14 MR. LOOBY: SO YOUR HONOR IS RIGHT THAT THERANOS HAD
01:53PM 15 MADE SEVERAL SUBMISSIONS, INCLUDING SUBMISSIONS WITH DATA ON
01:53PM 16 ITS ANALYZERS, ITS TESTS, AND INCLUDING ON TESTS RUN ON THE
01:53PM 17 CTN'S TO THE FDA OVER THE COURSE OF SEVERAL YEARS.

01:53PM 18 SO THE FDA'S INSPECTION OF THERANOS DIDN'T LOOK AT THOSE
01:54PM 19 RECORDS. THOSE ARE ACTUALLY KIND OF SEPARATE, AND, IN FACT,
01:54PM 20 CONTINUED AFTER THERANOS SUBMITTED A NEW 510(K) WITH NEW DATA
01:54PM 21 TO GET ITS CTN'S CLEARED, KIND OF IN THE MIDDLE OF WHILE THE
01:54PM 22 RECORD OF THE INSPECTION IS STILL GOING.

01:54PM 23 AND THERANOS CONTINUED TO ENGAGE WITH THE FDA ABOUT
01:54PM 24 GETTING EMERGENCY USE APPROVAL FOR ZIKA, Z-I-K-A, ASSAY IN
01:54PM 25 2016.

01:54PM 1 SO WHAT THE FDA INSPECTION WAS, WAS TO GO IN AND MAKE A
01:54PM 2 DETERMINATION THAT THE CTN'S ARE CLASS 2, AND SAY IF YOU'RE
01:54PM 3 DOING THAT, YOU NEED, LIKE -- YOU THOUGHT THAT YOU WERE AN LDT,
01:54PM 4 AND THAT'S WHAT THE INDICTMENT ALLEGATION IS ABOUT, BUT IN THE
01:54PM 5 PAST.

01:54PM 6 NOW WE'RE TELLING YOU YOU'VE GOT TO DO THESE QSR'S, YOU
01:54PM 7 DON'T HAVE YOUR DUCKS IN A ROW, AND WE'RE GOING TO WRITE YOU
01:54PM 8 UP.

01:54PM 9 BUT IT'S NOT ABOUT THAT THEY CAME IN AND THEY SAID, OH,
01:55PM 10 OH, WE'RE GOING TO REVIEW YOUR CLINICAL LAB TEST RESULTS. THEY
01:55PM 11 DIDN'T TO THAT. THAT'S A SEPARATE ORGANIZATION. AND THEY
01:55PM 12 ACTUALLY DIDN'T EVEN LOOK AT SOME OF THE VALIDATION WORK THAT
01:55PM 13 THERANOS HAD DONE ON ITS TESTS USING THE CTN'S BECAUSE THOSE
01:55PM 14 DOCUMENTS ARE MAINTAINED IN THE CLIA LAB CONTEXT. NOT OUR
01:55PM 15 JURISDICTION.

01:55PM 16 SO I DON'T THINK THERE'S QUITE A DIRECT LINE BETWEEN THE
01:55PM 17 TWO. THE FDA IS GOING TO BE IN THE CASE BUT THIS PART OF IT
01:55PM 18 COULD BE VERY EASILY EXCISED. IT HAS THE REAL POTENTIAL TO BE
01:55PM 19 QUITE THE SIDESHOW.

01:55PM 20 AND EVEN IF YOU TOOK AT FACE VALUE THAT THE TEXT MESSAGES
01:55PM 21 REFLECTED SOME FORM OF ANXIETY ABOUT THE FDA INSPECTION, IT
01:55PM 22 COULD BE THAT, YOU KNOW, WE HAVE BEEN GETTING ALONG WITH THE
01:55PM 23 FDA AND NOW THEY'RE HERE AND THAT -- I MEAN, THAT WOULD BE
01:55PM 24 TROUBLING. I MEAN, WE CURRENTLY HAVE SUBMISSIONS WITH THEM ON
01:55PM 25 FILE.

01:55PM 1 THE COURT: THERE'S A COMPLETE INNOCENT EXPLANATION
01:55PM 2 FOR ALL OF THIS.

01:55PM 3 MR. LOOBY: CORRECT. AND SO TO HAVE THESE KIND OF
01:56PM 4 AMBIGUOUS TEXT MESSAGES BE THE THING THAT DRAGS IN THIS ENTIRE
01:56PM 5 VIGNETTE ABOUT, YOU KNOW, ABOUT THE INSPECTION, TO ME IT JUST
01:56PM 6 SEEMS LIKE THAT JUICE IS DEFINITELY NOT WORTH THE SQUEEZE.

01:56PM 7 AND I THINK THE GOVERNMENT'S RELEVANCE THEORY FOR THESE
01:56PM 8 TEXT MESSAGES AND FOR THE ACTIONS AND RESPONSES, IT ALL KIND OF
01:56PM 9 PRESUPPOSES THAT THE FDA WAS THERE TO LIKE CRACK DOWN ON
01:56PM 10 THERANOS'S CLINICAL LABORATORY.

01:56PM 11 THE COURT: WELL, THIS IS WHY I WAS CURIOUS ABOUT --
01:56PM 12 I USED THE WORD "INVITEE." I'M NOT SUGGESTING THAT'S WHAT THEY
01:56PM 13 WERE. BUT IT WAS NOT UNUSUAL FOR THE FDA TO BE ON SITE DURING
01:56PM 14 THE CERTIFICATION PROCESS I GUESS. IT WAS UNUSUAL THAT THEY
01:56PM 15 DIDN'T CALL AND SAY THAT THEY WERE COMING, BUT --

01:56PM 16 MR. LOOBY: SO I'M NOT SURE THAT'S EXACTLY RIGHT,
01:56PM 17 YOUR HONOR. I THINK A LOT OF THE FDA SUBMISSIONS ARE DONE ON
01:56PM 18 THE PAPER. THERE'S A LOT OF PAPER IN THIS CASE WHEN I LOOK AT
01:56PM 19 THEM AND ON WEBEX'S, AND THEY WERE EVEN DOING ZOOM BACK IN THE
01:57PM 20 DAY.

01:57PM 21 SO I DON'T KNOW HOW MUCH OF AN ON SITE INSPECTION IS PART
01:57PM 22 OF THE FDA APPROVAL PROCESS. AND I DON'T THINK IT HAD BEEN UP
01:57PM 23 TO THIS POINT, AND THAT'S BECAUSE THIS INSPECTION WAS RELATED
01:57PM 24 TO THE FDA, LIKE THE MANUFACTURING DOCUMENTATION AND POLICIES,
01:57PM 25 AND NOT WITH THE, LIKE, REGULATORY APPROVAL APPLICATIONS.

01:57PM 1 THE COURT: SO YOU HAD PINNED THIS, I THINK, EARLIER
01:57PM 2 TO WHETHER OR NOT THIS INSPECTION CONNECTED WITH THE
01:57PM 3 INDICTMENT, THAT IS, THE ABILITY OF THERANOS TO PRODUCE
01:57PM 4 MACHINES THAT WOULD PRODUCE THEIR RELIABLE RESULTS
01:57PM 5 CONSISTENTLY. I THINK THAT'S WHAT YOU SAID EARLIER.

01:57PM 6 MR. LOOBY: YEAH.

01:57PM 7 THE COURT: LET ME TURN TO MR. LEACH.

01:57PM 8 IS THAT WHAT THIS IS ABOUT, MR. LEACH?

01:57PM 9 MR. LEACH: THIS IS ABOUT INTENT, YOUR HONOR, AND
01:57PM 10 THE DEFENDANT'S BELIEF THAT HER TECHNOLOGY, THE CTN, WAS PART
01:57PM 11 OF THERANOS TECHNOLOGY, PARTICULARLY IN THE APPLICATION HERE.
01:58PM 12 IT WAS NOT CAPABLE OF PRODUCING ACCURATE AND RELIABLE RESULTS.

01:58PM 13 THE CONTEXT HERE IS CRITICAL. JOHN CARREYROU IS TALKING
01:58PM 14 TO FORMER THERANOS EMPLOYEES ABOUT A STORY. MS. HOLMES IS
01:58PM 15 GOING TO "THE WALL STREET JOURNAL" BEGGING THEM NOT TO PUBLISH
01:58PM 16 THIS STORY BEFORE SEPTEMBER OF 2015. THEN IN SEPTEMBER OF 2015
01:58PM 17 THE FDA COMES KNOCKING.

01:58PM 18 WHAT IS HER REACTION TO ALL OF THIS? IS IT COME ON IN,
01:58PM 19 LOOK AT EVERYTHING, TOTALLY FINE, NOTHING TO SEE HERE, WE'RE
01:58PM 20 CONFIDENT IN HOW OUR CTN'S WORK, EVERYTHING IS GREAT, YOU CAN
01:58PM 21 HAVE EVERYTHING YOU WANT?

01:58PM 22 IT'S THE EXACT OPPOSITE. AND IT'S THE ANXIETY BETWEEN HER
01:58PM 23 AND HER PRIVATE COMMUNICATIONS BETWEEN HER AND HER CONSPIRATOR
01:58PM 24 ABOUT I'VE BEEN THINKING ABOUT TURNING THE CTN OFF. WE NEED TO
01:58PM 25 DEVOTE ALL AVAILABLE RESOURCES TO MAKING THIS BETTER. THOSE

01:58PM 1 ARE CRITICAL ADMISSIONS ABOUT ANXIETY ABOUT WHAT THE FDA MIGHT
01:58PM 2 FIND, ANXIETY ABOUT WHAT THEIR TECHNOLOGY COULD DO RIGHT AS
01:59PM 3 EVERYTHING IS COMING TO A HEAD.

01:59PM 4 SO WHETHER THIS WAS AFTER AN INVESTMENT, WHETHER THE FDA
01:59PM 5 WAS THERE JUST BECAUSE THEY WERE TAKING A RANDOM SAMPLE OF LABS
01:59PM 6 IN SILICON VALLEY AND JUST WANTED TO SAY HI DOESN'T MATTER.

01:59PM 7 WHAT MATTERS IS THE REACTION. AND THE REACTION, AND I
01:59PM 8 SUBMIT A FAIR READING OF THESE TEXTS, AND THEY MAY HAVE A SIDE
01:59PM 9 TO THAT STORY, BUT THAT'S FODDER FOR CROSS-EXAMINATION, IS
01:59PM 10 FREAKING OUT. WHAT DO WE DO ABOUT THIS? AND THAT'S VERY
01:59PM 11 RELEVANT TO STATE OF MIND AND BELIEVED IN THE ACCURACY AND THE
01:59PM 12 RELIABILITY OF THERANOS TECHNOLOGY.

01:59PM 13 THE COURT: ALL RIGHT. MR. LOOBY.

01:59PM 14 MR. LOOBY: YOUR HONOR, AGAIN, AND OBVIOUSLY THERE'S
01:59PM 15 A DIFFERENT WAY TO READ THESE TEXT MESSAGES, WHICH IS MAYBE WE
01:59PM 16 MIGHT TAKE THE CTN OFF AS WE MIGHT STOP USING THE CTN'S FOR OUR
01:59PM 17 LABORATORY DEVELOPED TESTS NOW THAT IT SEEMS LIKE FDA DOESN'T
01:59PM 18 AGREE WITH OUR POSITION ON THE LDT'S. SO WHY DON'T WE WAIT?
02:00PM 19 WE HAVE AN APPLICATION PENDING OR THEY WERE ABOUT TO RESUBMIT
02:00PM 20 ONE TO GET CLEARANCE FOR THEM. SO WHY DON'T WE DO THAT?

02:00PM 21 THE GOVERNMENT'S READING OF THESE ARE VERY CRIBBED, AND,
02:00PM 22 YOU KNOW, FOR THIS TO BE KIND OF THE WHOLE THING THAT JUSTIFIES
02:00PM 23 BRINGING THE FDA INSPECTION EVIDENCE, AND THEN TO SAY THAT A
02:00PM 24 LEGAL OBJECTIONS FROM THERANOS'S COUNSEL ARE, YOU KNOW, SOMEHOW
02:00PM 25 TERRIBLE INTENT EVIDENCE, TO ME IT'S QUITE THE STRETCH AND

02:00PM 1 WE'RE REALLY OUT ON A THIN READ OF RELEVANCE HERE.

02:00PM 2 THE COURT: OKAY. ALL RIGHT. THANK YOU BOTH VERY
02:00PM 3 MUCH. THANK YOU.

02:00PM 4 MR. LEACH: THANK YOU, YOUR HONOR.

02:00PM 5 THE COURT: THIS MOTION IS UNDER SUBMISSION. THANK
02:00PM 6 YOU.

02:00PM 7 I THINK 575 IS NEXT. IS THAT YOU?

02:01PM 8 MR. LOOBY: YES.

02:01PM 9 THE COURT: YOU'RE GETTING YOUR BILLABLES IN TODAY.

02:01PM 10 MR. LOOBY: YES. I'M THE REGULATORY GUY.

02:01PM 11 THE COURT: OKAY.

02:01PM 12 MR. LOOBY: SO THIS MOTION IS AT ECF 575 IT DEALS
02:01PM 13 WITH THREE DISCRETE SETS OF EVIDENCE THAT SHARE IN COMMON THEIR
02:01PM 14 INCLUSION ON THE GOVERNMENT'S 404(B) DISCLOSURE AS INVOLVING
02:01PM 15 SOME SORT OF DECEIT UPON A GOVERNMENT REGULATORY AGENCY.

02:01PM 16 AT THE THRESHOLD OF THIS, I WOULD JUST SAY THAT THE
02:01PM 17 GOVERNMENT HAS KIND OF WALKED -- TRIED TO WALK BACK FROM THE
02:01PM 18 404(B) CATEGORIZATION OF THIS IN THIS OPPOSITION AND IN MANY OF
02:01PM 19 ITS OPPOSITIONS.

02:01PM 20 I'LL JUST NOTE AT THE OUTSET, THE INDICTMENT DOES NOT
02:01PM 21 ALLEGE THAT THERE WAS ANY DECEIT UPON A GOVERNMENT AGENCY.
02:01PM 22 WE'VE GONE THROUGH BRIEFING IN THE MOTION TO DISMISS STAGE
02:01PM 23 ABOUT WHO THE VICTIMS ARE IN THIS CASE, THEY'RE NOT CDPH,
02:01PM 24 THEY'RE NOT FDA, THEY'RE NOT CMS. SO THIS IS PROPERLY
02:01PM 25 CONSIDERED 404(B) EVIDENCE, AND THE GOVERNMENT SHOULD HAVE TO

02:01PM 1 MEET 404 (B) STANDARDS.

02:02PM 2 SO I'LL BE ADDRESSING THE EVIDENCE THROUGH THAT FRAMEWORK,
02:02PM 3 AND I CAN TAKE QUESTIONS FROM YOUR HONOR IN A DIFFERENT
02:02PM 4 FRAMEWORK, TOO.

02:02PM 5 SO HERE ARE THE THREE BUCKETS OF EVIDENCE THAT WE'RE GOING
02:02PM 6 TO BE TALKING ABOUT TO TODAY: THERE'S EVIDENCE RELATED TO A
02:02PM 7 DECEMBER 2013 INSPECTION OF THERANOS CLIA LABORATORY BY A
02:02PM 8 CALIFORNIA STATE AGENCY. THAT'S KIND OF AN AGENT OF CMS;

02:02PM 9 THERE'S A LETTER PROVIDED BY MR. BALWANI TO CMS DURING
02:02PM 10 THE 2015 INSPECTION THAT WE'VE BEEN TALKING ABOUT; AND,

02:02PM 11 FINALLY, THERE'S FACTS SURROUNDING ONE OF THERANOS'S
02:02PM 12 LABORATORY DIRECTORS, DR. SUNIL DHAWAN.

02:02PM 13 THE COURT: D-H-A-W-A-N.

02:02PM 14 MR. LOOBY: THAT'S CORRECT, YOUR HONOR.

02:02PM 15 I'LL PROCEED IN THAT ORDER, BUT I CAN CERTAINLY ENTERTAIN
02:02PM 16 QUESTIONS OUT OF THAT ORDER IF THAT'S YOUR HONOR'S PREFERENCE.

02:02PM 17 THE COURT: THAT'S FINE.

02:02PM 18 MR. LOOBY: SO JUST A LITTLE BACKGROUND ON THE 2013
02:02PM 19 INSPECTION. SO AS I SAID, THE CALIFORNIA DEPARTMENT OF PUBLIC
02:02PM 20 HEALTH LAB FIELD SERVICES DIVISION, THEY ARE CMS'S AGENTS FOR
02:03PM 21 KIND OF ROUTINE RECERTIFICATION SURVEYS OF CLIA LABS HERE IN
02:03PM 22 CALIFORNIA. THESE GENERALLY OCCUR EVERY TWO YEARS. THERANOS'S
02:03PM 23 TIME FOR A RENEWAL INSPECTION CAME UP IN 2013. THE CDPH
02:03PM 24 INSPECTION FOLLOWS THE SAME CONTOURS AS THE CMS INSPECTION THAT
02:03PM 25 WE TALKED ABOUT EARLIER.

02:03PM 1 THE KEY IS THAT THE INSPECTOR FOR CDPH, LIKE FOR CMS,
02:03PM 2 THEY'RE IN CHARGE OF WHAT DOCUMENTS THEY WANT TO LOOK AT, THEY
02:03PM 3 ARE IN CHARGE OF DETERMINING, YOU KNOW, HOW MUCH EVIDENCE THEY
02:03PM 4 WANT TO REVIEW TO GET COMFORTABLE THAT THE LAB IS EITHER
02:03PM 5 COMPLIANT OR TO GET COMFORTABLE THAT THEY HAVE ENOUGH
02:03PM 6 INFORMATION TO MAKE A DEFICIENCY CLAIM.

02:03PM 7 SO THE GOVERNMENT'S PROPOSED EVIDENCE HERE, IT RELIES ON
02:03PM 8 CONTORTING A FEW EMAILS OUT OF CONTEXT TO SUGGEST THAT
02:03PM 9 MS. HOLMES WAS INVOLVED IN STEERING THE INSPECTOR, CDPH
02:03PM 10 INSPECTOR, AWAY FROM AN AREA OF THE LAB WHERE THE THREE SERIES
02:04PM 11 TSPU WAS LOCATED.

02:04PM 12 SO AS AN INITIAL MATTER, THE GOVERNMENT HAS NOT
02:04PM 13 ESTABLISHED THAT LIKE NOT LEADING AN INSPECTOR TO A CERTAIN
02:04PM 14 AREA OF THE LAB DURING AN INSPECTION IS INHERENTLY DECEPTIVE.

02:04PM 15 AS WE DISCUSSED EARLIER, THAT'S NOT HOW LAB INSPECTIONS
02:04PM 16 WORK. AND THE GOVERNMENT LARGELY IGNORES THAT POINT IN ITS
02:04PM 17 OPPOSITION, BUT I THINK IT'S IMPORTANT TO KEEP IN MIND.

02:04PM 18 THE SECOND PROBLEM WITH THE THEORY, I MEAN MAYBE THIS IS
02:04PM 19 THE FIRST PROBLEM WITH THE THEORY, BUT THAT IT'S CONTRADICTED
02:04PM 20 BY ALL AVAILABLE EVIDENCE AS WELL AS COMMON SENSE.

02:04PM 21 SO HERE'S WHAT WE KNOW ABOUT WHAT HAPPENED. SO IN
02:04PM 22 PREPARING FOR THE INSPECTION THERANOS MADE SURE THAT IT HAD ITS
02:04PM 23 LDT DATA AND DOCUMENTS READY FOR INSPECTION.

02:04PM 24 AND WE KNOW THIS BECAUSE IT'S IN THE GOVERNMENT'S OWN
02:04PM 25 EXHIBIT 28, AND THAT'S AT ECF 680-14. THAT IS AN EMAIL ABOUT

02:05PM 1 WHAT DO WE NEED TO GET OUR DUCKS IN A ROW SO THAT WE'RE READY
02:05PM 2 FOR INSPECTION BECAUSE THESE ARE SCHEDULED INSPECTIONS.

02:05PM 3 SO WE ALSO KNOW THAT THIS LDT DATA WAS IN FACT SHARED WITH
02:05PM 4 THE INSPECTOR UPON HER REQUEST. THIS COMES FROM DEFENSE
02:05PM 5 EXHIBIT 77 AT ECF 772-3. AND THESE ARE THERANOS'S EMPLOYEE,
02:05PM 6 DANIEL YOUNG'S, NOTES OF THE AUDIT. AND THEY DISCUSS KIND OF
02:05PM 7 WHAT THEY WENT OVER WITH THE INSPECTOR, AND IT INCLUDES A
02:05PM 8 DISCLOSURE THAT TESTS ARE BEING RUN ON THE TSPU, THAT TESTS ARE
02:05PM 9 BEING RUN ON BLOOD SAMPLES COLLECTED BY THE CTN'S, THAT THESE
02:05PM 10 ARE BEING OFFERED AS LABORATORY DEVELOPED TESTS, AND THAT THEY
02:05PM 11 ARE BEING VALIDATED AS LABORATORY DEVELOPED TESTS AND UPON THE
02:05PM 12 INSPECTOR'S REQUEST, WHICH SHE RANDOMLY SELECTED AN LDT
02:05PM 13 VALIDATION REPORT, WHICH WAS PROVIDED TO HER. SO THAT'S ALL IN
02:05PM 14 THAT EXHIBIT.

02:05PM 15 SO WE ALSO KNOW, AND THIS IS THE THIRD PIECE OF EVIDENCE,
02:06PM 16 WE KNOW THAT MONTHS PRIOR TO THIS INSPECTION, THERANOS HAD
02:06PM 17 ALREADY DISCLOSED TO CMS, WHICH SITS ON TOP OF THIS REGULATORY
02:06PM 18 SCHEME, THAT IT WAS USING THE TSPU IN ITS LAB TO TEST PATIENT
02:06PM 19 SAMPLES.

02:06PM 20 THIS COMES FROM DEFENSE EXHIBIT 78 AT ECF 722-4. AND
02:06PM 21 THESE ARE MINUTES OF A NOVEMBER 4TH, 2013 MEETING OF WHICH
02:06PM 22 MEMBERS OF THE FDA AND THE CMS WERE PRESENT DURING WHICH
02:06PM 23 THERANOS'S CURRENT AND FUTURE BUSINESS MODELS WERE DISCUSSED.

02:06PM 24 SO THAT'S ALL OF THE EVIDENCE THAT REALLY SHOULD KIND OF
02:06PM 25 END THE MATTER HEAR.

02:06PM 1 BUT THERE'S A THIRD PROBLEM WITH THIS THEORY, AND THAT IS
02:06PM 2 THERE'S NO CONNECTION BETWEEN THIS EMAIL, THE DANIEL YOUNG
02:06PM 3 EMAIL, TO MADAM ROSENDORFF WHICH SAYS SOMETHING ALONG THE LINES
02:06PM 4 OF LET'S NOT REMIND HER ABOUT DOWNSTAIRS AT THIS POINT.

02:07PM 5 THERE'S NO CONNECTION BETWEEN THAT EMAIL AND MS. HOLMES.

02:07PM 6 SO THE GOVERNMENT CITES A FEW EMAILS FROM MS. HOLMES OR ON
02:07PM 7 WHICH SHE'S COPIED DISCUSSING THE PREPARATIONS FOR THE AUDIT
02:07PM 8 FOR THE PROPOSITION THAT SHE IS GENERALLY INFORMED THAT THE
02:07PM 9 AUDIT WAS HAPPENING AND INTERESTED THAT PEOPLE IN THE
02:07PM 10 LABORATORY WERE PREPARING FOR IT.

02:07PM 11 AND THEY ARGUE ESSENTIALLY, WELL, IT STANDS TO REASON THAT
02:07PM 12 SHE'S INVOLVED IN THE AUDIT PREPARATION, AND SO SHE MUST BE
02:07PM 13 BEHIND THIS INSTRUCTION FROM YOUNG TO ROSENDORFF. THIS MUST BE
02:07PM 14 HIM COMMUNICATING A COMMAND FROM HER.

02:07PM 15 SO THAT'S -- TO THE DEFENSE'S KNOWLEDGE, YOUNG NOR
02:07PM 16 ROSENDORFF WILL TESTIFY TO THIS. THEY CERTAINLY HAVEN'T SAID
02:07PM 17 SO IN THEIR PRIOR STATEMENTS.

02:07PM 18 SO WHERE DOES THAT LEAVE US? IT LEAVES US IN A LAND OF
02:07PM 19 SPECULATION. WE'RE SPECULATING ABOUT AMBIGUOUS EMAILS ABOUT
02:07PM 20 THE PATH THE REGULATOR WILL TAKE, WE'RE SPECULATING THAT THAT
02:07PM 21 MS. HOLMES WAS SOMEHOW INVOLVED, WE'RE SPECULATING THAT THIS
02:08PM 22 WAS MOTIVATED BY A DESIRE TO HIDE THINGS THAT WERE ACTUALLY
02:08PM 23 BEING DISCLOSED.

02:08PM 24 SO THE COURT SHOULD NIP THIS EXERCISE AND SPECULATION IN
02:08PM 25 THE BUD, AND THAT'S THE THRUST OF OUR ARGUMENT THERE. AS WE

02:08PM 1 POINTED OUT IN OUR REPLY BRIEF, THERE COMES A POINT WHERE YOU
02:08PM 2 STACK SO MANY CONNECTIONS ON TOP OF EACH OTHER THAT THE BONDS
02:08PM 3 BREAK, AND THE EVIDENCE IS NO LONGER REALLY RELEVANT AT THAT
02:08PM 4 POINT. AND IT CAN'T BE THE ANSWER THAT IN ALL OF THESE
02:08PM 5 INSTANCES, OH, IT'S FOR THE JURY. IT'S REALLY THE GOVERNMENT
02:08PM 6 DISCLOSED THIS UNDER RULE 404(B). WHEN THEY DO THAT, THEY HAVE
02:08PM 7 TO CONNECT IT TO THE DEFENDANT, THEY HAVE TO MAKE SURE IT
02:08PM 8 CONNECTS TO A MATERIAL FACT IN THE CASE, AND THEY HAVE TO
02:08PM 9 OVERCOME AN EVEN MORE HEIGHTENED 403 BALANCING TEST THAT
02:08PM 10 APPLIES IN THE 404(B) CONTEXT, AND WE SUBMIT THAT THEY HAVE NOT
02:08PM 11 COME CLOSE TO THAT FACT.

02:09PM 12 SO UNLESS YOUR HONOR HAS QUESTIONS, I'LL MOVE ON TO THE
02:09PM 13 NEXT PIECE OF EVIDENCE. SO THIS IS THE 2015 LETTER. THIS IS
02:09PM 14 KIND OF ANOTHER PECULIAR CASE AND ACCORDING TO THE GOVERNMENT
02:09PM 15 IT WAS HAND DELIVERED TO CMS DURING THE 2015 INSPECTION BY
02:09PM 16 MR. BALWANI.

02:09PM 17 THE GOVERNMENT -- THE LETTER ITSELF IS AT GOVERNMENT
02:09PM 18 EXHIBIT 6 TO THEIR OPPOSITION, AND THAT'S AT ECF 679-6. WE
02:09PM 19 MOVE TO EXCLUDE IT BECAUSE AS DISCLOSED IT'S ENTIRELY UNRELATED
02:09PM 20 TO MS. HOLMES. IT'S NOT SIGNED.

02:09PM 21 AGAIN, THIS IS RULE 404(B) EVIDENCE, AND ONE OF THE
02:09PM 22 REQUIREMENTS IS THAT THEY CONNECT IT, IN THE NINTH CIRCUIT IS
02:09PM 23 THAT THEY CONNECT IT TO MS. HOLMES. IT SEEMS LIKE A REASONABLE
02:09PM 24 THING THAT THEY ASK THE GOVERNMENT TO DO.

02:09PM 25 BUT IN RESPONSE THEY DO THE SAME THING THAT THEY DO WITH

02:09PM 1 THE 2013 EMAIL FROM DANIEL YOUNG, WHICH IS THAT THEY POINT TO
02:09PM 2 OTHER UNRELATED INSTANCES WHERE MS. HOLMES IS INVOLVED OR AWARE
02:10PM 3 OF THE CMS INTERACTIONS WITH THE COMPANY AND EVEN STRANGELY
02:10PM 4 WITH FDA FACTS, TOO.

02:10PM 5 AND THEY SAY, WELL, OKAY, IT STANDS TO REASON THAT SHE WAS
02:10PM 6 BEHIND THIS LETTER OR ADOPTED IT AND ANY ALLEGED
02:10PM 7 MISREPRESENTATION IN IT. THAT SPECULATIVE LINK, WE SUBMIT, IS
02:10PM 8 INSUFFICIENT TO JUSTIFY ADMISSION AT LEAST ON THE BASIS THAT
02:10PM 9 IT'S BEEN PROFFERED SO FAR. WE THINK THE GOVERNMENT HAS NOT
02:10PM 10 MET ITS BURDEN.

02:10PM 11 FINALLY, ONE LAST POINT ON THIS LETTER IS THAT THE
02:10PM 12 GOVERNMENT'S PROPOSED USE OF THIS AS 404(B) EVIDENCE, IT
02:10PM 13 DOESN'T MAKE A WHOLE LOT OF SENSE TO ME, AND IT SUGGESTS THAT
02:10PM 14 IT'S NOT BEING USED TO PROVE A MATERIAL FACT, WHICH IS ONE OF
02:10PM 15 THE FACTORS IN THE 404(B) ANALYSIS BECAUSE ON THE ONE HAND THE
02:10PM 16 GOVERNMENT WANTS TO USE PART IT, OR PART OF THE LETTER THAT
02:10PM 17 LISTS THE DATES THAT TESTS WERE RUN ON THE TSPU IN THE CLINICAL
02:10PM 18 LAB. THEY'RE OFFERING IT AS A TRUTHFUL STATEMENT TO THE AGENCY
02:10PM 19 ACCORDING TO THEIR OPPOSITION.

02:10PM 20 BUT ON THE OTHER HAND, IT POINTS TO A STATEMENT THAT TESTS
02:11PM 21 ARE CYCLED OFF THE TSPU OVER TIME FOR BUSINESS REASONS. IT
02:11PM 22 CALLS IT SELF-SERVING AND MISLEADING.

02:11PM 23 IT'S NOT REALLY CLEAR TO ME HOW THIS KIND OF THROWAWAY
02:11PM 24 LINE IN A LETTER WOULD DECEIVE AN AGENCY THAT AT THAT VERY
02:11PM 25 MOMENT WAS INSPECTING THERANOS AND KIND OF HAD FREE REIN TO

02:11PM 1 INSPECT WHAT IT WANTED TO LOOK AT INCLUDING ANY QC DATA OR ANY
02:11PM 2 LAB DOCUMENTATION RELATED TO THE LDT'S.

02:11PM 3 SO FOR ALL OF THESE REASONS THE EVIDENCE IS MORE LIKELY TO
02:11PM 4 DISTRACT AND CONFUSE RATHER THAN TO ENLIGHTEN, AND IT SHOULD BE
02:11PM 5 EXCLUDED.

02:11PM 6 AND FINALLY WE GET TO DR. SUNIL DHAWAN. SO IN LATE 2013
02:11PM 7 THERANOS HIRED DR. SUNIL DHAWAN AS THE LABORATORY DIRECTOR. AT
02:11PM 8 THE SAME TIME THEY ALSO HIRED ANOTHER CO-LAB DIRECTOR, AND THIS
02:11PM 9 IS A WOMAN BY THE NAME OF DR. LYNETTE SAWYER. NOW BOTH WERE
02:11PM 10 QUALIFIED TO SERVE AS CLIA LAB DIRECTORS IN THE STATE OF
02:12PM 11 CALIFORNIA, AND THAT'S NOT CONTESTED.

02:12PM 12 NEITHER OF THEM SERVED AS FULL-TIME LAB DIRECTORS AS IN
02:12PM 13 THEY WEREN'T PRESENT ON THERANOS'S CAMPUS FULL TIME.

02:12PM 14 THAT'S ENTIRELY APPROPRIATE UNDER THE CLIA REGULATIONS,
02:12PM 15 AND IT'S ACTUALLY NOT OUT OF THE ORDINARY IN THE LAB INDUSTRY
02:12PM 16 AS I UNDERSTAND IT.

02:12PM 17 NOW, SOME LABS THEY MIGHT HAVE A LAB DIRECTOR WHO IS ON
02:12PM 18 THE GROUND AND WORKS ON A NORMAL 40-HOUR WORKWEEK IN THE LAB.

02:12PM 19 BUT THE CLIA REGULATIONS, THEY TREAT THE LAB DIRECTOR AS
02:12PM 20 KIND OF THE LEGAL FIGUREHEAD OR REPOSITORY OF WHERE ALL OF THE
02:12PM 21 OBLIGATIONS LAND. LIKE THE BUCK STOPS WITH HIM.

02:12PM 22 BUT A LOT OF THE DAY-TO-DAY OPERATIONS ARE PERMISSIBLY
02:12PM 23 DELEGATED TO THE STAFF THAT SITS UNDERNEATH THE LAB DIRECTOR.

02:12PM 24 SO THE GOVERNMENT DOESN'T CONTEST THESE FACTS, EITHER.

02:12PM 25 THE GOVERNMENT NONETHELESS, THEY WANT TO ASK THE JURY TO

02:12PM 1 DRAW A SERIES OF INFERENCES FROM HIS RETENTION AND FACTS ABOUT
02:12PM 2 HIM THAT REQUIRES THEM TO IGNORE THESE FACTS.

02:13PM 3 SO THE INFERENCE IN PARTICULAR THAT THEY WANT TO DRAW IS
02:13PM 4 THE FACT OF HIS RETENTION SHOWS THAT MS. HOLMES WAS INDIFFERENT
02:13PM 5 TO LAB QUALITY ALTOGETHER.

02:13PM 6 I JUST DON'T SEE HOW THE GOVERNMENT CAN USE THE EVIDENCE
02:13PM 7 IN THAT WAY WITHOUT IMPLYING THAT THOSE TWO UNCONTESTED FACTS,
02:13PM 8 THAT HE WAS QUALIFIED AND THAT THERE WAS NOTHING NECESSARILY
02:13PM 9 IMPROPER ABOUT HIS PART-TIME STATUS, LIKE WITHOUT HAVING THE
02:13PM 10 JURY KIND OF IGNORE THOSE.

02:13PM 11 SO REALLY THIS IS AN IMPROPER USE OF THIS EVIDENCE UNDER
02:13PM 12 RULE 404(B) OR OTHERWISE REALLY AND THE COURT SHOULD PRECLUDE
02:13PM 13 IT.

02:13PM 14 THE COURT: ALL RIGHT. THANK YOU.

02:13PM 15 MR. LEACH, IS THIS YOUR DAY ALSO?

02:13PM 16 MR. LEACH: IT IS MY DAY, YOUR HONOR. YES.

02:13PM 17 THE COURT: SO I LOOKED AT THIS INITIALLY,
02:13PM 18 MR. LEACH, AND I WAS CURIOUS WHAT IS THE 404(B) USE HERE? WHAT
02:13PM 19 IS THE 404(B) ANALYSIS THAT THE GOVERNMENT IS SEEKING? AND I'M
02:14PM 20 SURE YOU'LL TELL ME ABOUT THAT.

02:14PM 21 MR. LEACH: YES. INTENT, PLAN, KNOWLEDGE, STATE OF
02:14PM 22 MIND, AND TO SOME EXTENT MOTIVE, YOUR HONOR. I'LL GO IN
02:14PM 23 REVERSE ORDER BECAUSE IT'S FRESHEST IN MY MIND AND PERHAPS THE
02:14PM 24 COURT'S.

02:14PM 25 NOVEMBER OF 2014 THERANOS WAS IN CRISIS. THEIR LAB

02:14PM 1 DIRECTOR WOULD NO LONGER PUT HIS NAME ON THE RESULTS BEING
02:14PM 2 GENERATED BY THE CLIA LAB. HE RESIGNED BASICALLY OUT OF
02:14PM 3 CONCERNS THAT THERANOS WAS TURNING A BLIND EYE TO ALL OF THE
02:14PM 4 PROBLEMS IN ITS LAB.

02:14PM 5 THE COURT: IS THIS DR. ROSENDORFF?

02:14PM 6 MR. LEACH: THIS IS DR. ROSENDORFF.

02:14PM 7 WHAT DID THERANOS DO ABOUT IT? THEY APPROACHED
02:14PM 8 MR. BALWANI'S DERMATOLOGIST, WHO HAS NO EXPERIENCE IN A HIGH
02:14PM 9 COMPLEXITY LAB OTHER THAN HIS DERMATOLOGY PRACTICE, AND SAY YOU
02:14PM 10 WON'T HAVE TO DO ANY WORK, THIS WON'T DISTRACT FROM YOUR
02:15PM 11 PRACTICE, PLEASE COME BE OUR LAB DIRECTOR IN SUBSTANCE. THIS
02:15PM 12 DRAGS ON FOR ABOUT SIX MONTHS, WHICH SHOWS THAT THESE TWO
02:15PM 13 DEFENDANTS ARE NOT TERRIBLY CONCERNED ABOUT FIXING THE BAD
02:15PM 14 RESULTS COMING OUT OF THEIR LAB.

02:15PM 15 AND THEY HAGGLE WITH DR. DHAWAN OVER WHAT HE'S GOING TO BE
02:15PM 16 PAID. AND THEY ESSENTIALLY ASSURE HIM YOU'LL GET PAID, BUT YOU
02:15PM 17 WON'T HAVE TO DO ANY WORK, IT WON'T DISTRACT FROM YOUR
02:15PM 18 PRACTICE, AND IT'S ALL VERY MINIMAL.

02:15PM 19 AND THE VERY FIRST DAY THAT DR. DHAWAN STEPS INTO THE LAB
02:15PM 20 IS THE DAY THAT THE CMS INSPECTORS SHOW UP FOR THEIR
02:15PM 21 INSPECTION.

02:15PM 22 WE THINK THIS CHRONOLOGY OF HOW DR. DHAWAN WAS HIRED, WHAT
02:15PM 23 HE WAS TOLD, THE URGENCY WITH WHICH THEY'RE TRYING TO ADDRESS
02:15PM 24 THESE VERY ISSUES THAT DR. ROSENDORFF RAISED IN THE LAB ARE
02:15PM 25 RELEVANT TO THEIR INTENT UNDER 403, 404(B) OR ANY OTHER

02:16PM 1 RELEVANCE STANDARD.

02:16PM 2 THE REASON THAT FLOWS IS THAT YOU CAN HIRE SOMEBODY WHO IS
02:16PM 3 QUALIFIED, BUT SOMEBODY WHO IS NOT THE SUPERSTAR YOU WANT TO
02:16PM 4 FIX YOUR LAB. AND YOU SEE THAT BY COMPARISON OF WHO THE
02:16PM 5 DEFENDANTS HIRE TO SUE EMPLOYEES WHO THEY THINK ARE BREACHING
02:16PM 6 THEIR AGREEMENTS TO DEAL WITH "THE WALL STREET JOURNAL." THEY
02:16PM 7 HIRED DAVID BOIES TO TRY TO INTIMIDATE "THE WALL STREET
02:16PM 8 JOURNAL" TO BACK OFF FROM PUBLISHING THEIR ARTICLE.

02:16PM 9 THEY HIRED MR. BALWANI'S DERMATOLOGIST TO MAKE SURE THAT
02:16PM 10 THEIR HCG TESTS WERE CORRECT AND TOLD HIM THAT YOU DON'T EVEN
02:16PM 11 NEED TO COME INTO THE LAB, WE'LL PAY YOU ANYWAYS. ALL THAT IS
02:16PM 12 RELEVANT TO HOW SERIOUSLY THESE DEFENDANTS TOOK THEIR
02:16PM 13 STATEMENTS ABOUT ACCURATE RELIABLE TESTS COMING OUT OF THE LAB.

02:16PM 14 THE COURT: I'M SORRY. WILL THERE BE EVIDENCE THAT
02:16PM 15 THAT'S WHAT HE WAS TOLD, THE DOCTOR WAS TOLD?

02:16PM 16 MR. LEACH: YES. THERE'S AN EMAIL FROM
02:16PM 17 SUNNY BALWANI TO DR. DHAWAN SAYING YOU WON'T HAVE TO DO MUCH
02:17PM 18 WORK, AND HE'S PAID ALL OF THE WAY THROUGH JUNE.

02:17PM 19 THE PAPERWORK FOR HIM BECOMING THE LAB DIRECTOR ISN'T
02:17PM 20 SUBMITTED UNTIL JUNE. SO THERE WILL BE EVIDENCE ALONG THOSE
02:17PM 21 LINES.

02:17PM 22 WITH RESPECT TO THE 2015 CMS INSPECTION, THE DOCUMENT
02:17PM 23 WE'RE TALKING ABOUT IS HIGHLY RELEVANT. IT'S AN ADMISSION --
02:17PM 24 FIRST OF ALL, THE TESTIMONY WILL BE FROM SARAH BENNETT THAT
02:17PM 25 MR. BALWANI HANDED HER -- HANDED MS. BENNETT THE DOCUMENTS

02:17PM 1 DURING THE CMS INSPECTION. AND THE DOCUMENT IS ESSENTIALLY AN
02:17PM 2 ADMISSION ABOUT WHAT TEST THERANOS WAS USING THE EDISON FOR
02:17PM 3 DURING WHAT PERIODS OF TIME. THAT PART THE GOVERNMENT WILL BE
02:17PM 4 OFFERING FOR ITS TRUTH. IT'S A STATEMENT BY AN AGENT OF
02:18PM 5 MS. HOLMES. IT'S HER CEO, SOMEBODY SHE WORKS WITH CLOSELY.

02:18PM 6 AND THE THRUST OF THE GOVERNMENT'S EVIDENCE IN THE
02:18PM 7 OPPOSITION IS GIVEN THE ANXIETY GOING ON OVER THE CMS
02:18PM 8 INSPECTION, GIVEN THAT MS. HOLMES WAS PRAYING DURING THE EXAM
02:18PM 9 OR DURING THE INSPECTION FOR IT TO GO WELL, THAT THE FAIR
02:18PM 10 INFERENCE IS THAT SHE'S IN COMMUNICATION WITH MR. BALWANI ABOUT
02:18PM 11 WHAT IS BEING TOLD TO CMS. I THINK THESE ARE FAIRLY STATEMENTS
02:18PM 12 OF AN AGENT. AND WE DON'T NEED TO PROVE 404(B) EVIDENCE BEYOND
02:18PM 13 A REASONABLE DOUBT. IT'S SIMPLY SUFFICIENT EVIDENCE FOR A
02:18PM 14 FINDING, AND I THINK THAT'S THERE.

02:18PM 15 THE OTHER PORTION OF THIS LETTER IS A STATEMENT TO CMS TO
02:18PM 16 THE EFFECT OF WE DIDN'T STOP DOING THE TESTING BECAUSE OF
02:18PM 17 ACCURACY AND RELIABILITY CONCERNS. WE MADE A BUSINESS DECISION
02:18PM 18 TO RETIRE THESE DOCUMENTS -- OR THESE DEVICES.

02:18PM 19 WE THINK THAT'S FALSE. WE THINK THAT'S SAID TO THE CMS
02:18PM 20 INSPECTORS IN ORDER TO ALLAY THEIR CONCERNS, TO MINIMIZE THEIR
02:19PM 21 INSPECTION, TO ESSENTIALLY DETER THEM FROM REALLY OPENING UP
02:19PM 22 THE HOOD.

02:19PM 23 THIS IS UNDOUBTEDLY A STATEMENT BY MR. BALWANI WHO IS THE
02:19PM 24 DEFENDANT'S COCONSPIRATOR. THIS IS CLEARLY A STATEMENT IN
02:19PM 25 FURTHERANCE OF THE CONSPIRACY TO AVOID DETECTION BY REGULATORY

02:19PM 1 AUTHORITIES.

02:19PM 2 SO UNDER 404(B) AND 403, I THINK THIS IS CLEARLY RELEVANT
02:19PM 3 TO THE EXISTENCE OF AN AGREEMENT, THE STATE OF MIND OF THE
02:19PM 4 DEFENDANT. IT'S BOTH A TRUE STATEMENT ABOUT WE'LL OFFER IT FOR
02:19PM 5 THE TRUTH OF WHAT TESTS THERANOS WAS ACTUALLY DOING IT, BUT WE
02:19PM 6 WILL ALSO SAY THAT THIS STATEMENT ABOUT WE JUST MADE A BUSINESS
02:19PM 7 DECISION IS A WAY TO DETER CMS FROM ACTUALLY LOOKING UNDER THE
02:19PM 8 HOOD.

02:19PM 9 THE THIRD CATEGORY THAT MY FRIEND TALKED ABOUT IS THE 2013
02:20PM 10 CALIFORNIA STATE INSPECTION. THIS IS ALSO RELEVANT UNDER 401
02:20PM 11 AND 402. IT'S NOT 403. TO THE EXTENT IT'S 404(B), IT MEETS
02:20PM 12 ALL OF THE STANDARDS. IT'S OFFERED FOR THE DEFENDANT'S INTENT,
02:20PM 13 STATE OF MIND, PLAN, AND MOTIVE.

02:20PM 14 I THINK ONE OF THE EMAILS IS FROM DR. YOUNG TO
02:20PM 15 DR. ROSENDORFF ESSENTIALLY SAYING LET'S NOT REMIND THE
02:20PM 16 INSPECTOR OF THE DOWNSTAIRS LAB. THE DOWNSTAIRS LAB IS WHERE
02:20PM 17 THEY HAD SOME SIEMENS MACHINES, SOME THIRD PARTY MACHINES, BUT
02:20PM 18 ALSO THE EDISON MACHINES THAT THEY WERE THEN USING IN THEIR
02:20PM 19 CLIA LAB.

02:20PM 20 WE THINK THE FAIR INFERENCE FROM THIS EMAIL, WHICH WE
02:20PM 21 CONNECT THROUGH DR. YOUNG AS A DIRECTION FROM MR. BALWANI, THE
02:20PM 22 COCONSPIRATOR, IS REFLECTED OF THE DESIRE ON THERANOS'S PART TO
02:21PM 23 NOT SHOW THE REGULATORS THE SECRET SAUCE. IT'S REFLECTIVE OF
02:21PM 24 THEIR INTENT, STATE OF MIND.

02:21PM 25 A WITNESS, ELENITOBA JOHNSON, I ANTICIPATE WILL SAY SHE

02:21PM 1 TOOK ONE OF MS. HOLMES'S EMAILS AS A DIRECTION NOT TO SHOW THE
02:21PM 2 INSPECTORS THE DOWNSTAIRS LAB.

02:21PM 3 AND THE FACT THAT THEY MAY HAVE DISCLOSED SOME INFORMATION
02:21PM 4 TO CMS IN D.C. AT SOME POINT IN TIME OR THAT DR. YOUNG'S FIELD
02:21PM 5 NOTES SHOW THAT DESPITE THE DEFENDANT'S CONCERN ABOUT SECRECY
02:21PM 6 AND THE CONCERN ABOUT SHOWING THIS, THEY DISCLOSED SOME
02:21PM 7 INFORMATION ANYWAY, DOESN'T REALLY CUT AGAINST THE CORE ISSUE
02:21PM 8 WHICH WAS WHAT WAS HER STATE OF MIND WHEN SHE TOLD HER
02:21PM 9 EMPLOYEES DON'T TAKE THE INSPECTORS DOWN THERE?

02:21PM 10 AND IF SHE WERE PROUD OF HER TECHNOLOGY, IF SHE WAS
02:21PM 11 CONFIDENT IN IT, SHE WANTED TO SHOW EVERYBODY THE GREAT
02:21PM 12 INVENTION THAT SHE HAD MADE, SHE WOULD HAVE SAID SOMETHING
02:22PM 13 DIFFERENTLY, THE GOVERNMENT SUBMITS.

02:22PM 14 WE THINK THIS IS REFLECTIVE OF AN INTENT TO CONCEAL, AN
02:22PM 15 INTENT TO HIDE, AND WE DON'T NEED TO PROVE 404(B) EVIDENCE
02:22PM 16 BEYOND A REASONABLE DOUBT. WE NEED TO HAVE SUFFICIENT EVIDENCE
02:22PM 17 TO SUPPORT THE JURY'S FINDING. THAT'S IN THE CASE LAW WE LAY
02:22PM 18 OUT IN THE BRIEF.

02:22PM 19 AND I THINK THE COMBINATION OF THE EMAILS, DR. YOUNG
02:22PM 20 SAYING THAT MY DIRECTION TO ROSENDORFF CAME FROM BALWANI, AND
02:22PM 21 EMAILS FROM MS. HOLMES CONSISTENT WITH THAT, AND MS. JOHNSON'S
02:22PM 22 STATEMENT ARE MORE THAN SUFFICIENT TO GET THIS IN.

02:22PM 23 THE OTHER THING THAT WE DIDN'T TALK ABOUT IS THERE ARE
02:22PM 24 FINDINGS FROM THE INSPECTION IN 2013 GOING TO THE EXTENT OF
02:22PM 25 THERANOS'S QUALITY ASSESSMENT PROGRAM. THOSE ARE OFFERED TO

02:22PM 1 SHOW NOTICE TO THE DEFENDANT. SOME OF THE ISSUES THAT COME UP
02:22PM 2 IN THIS 2013 INSPECTION ALSO ARISE IN 2015. SO THAT DOCUMENT
02:23PM 3 IS ADMISSIBLE FOR THE NONHEARSAY PURPOSE OF NOTICE TO THE
02:23PM 4 DEFENDANT.

02:23PM 5 THE COURT: ALL RIGHT.

02:23PM 6 MR. LEACH: IF THE COURT HAS NO FURTHER QUESTIONS,
02:23PM 7 I'LL SUBMIT IT.

02:23PM 8 THE COURT: NO. THANK YOU.

02:23PM 9 MR. LOOBY: SO I THINK I ALSO WILL START WITH THE
02:23PM 10 LAST TOPIC, AND WE'LL WORK OUR WAY BACKWARDS.

02:23PM 11 SO, YOUR HONOR, THE GOVERNMENT STILL -- WHAT I DIDN'T HEAR
02:23PM 12 THERE IS ANY CONNECTION BETWEEN THE EVIDENCE THAT THEY HAVE
02:23PM 13 PROFFERED TO USE, THE EMAIL FROM YOUNG TO MS. HOLMES, SAYING
02:23PM 14 THAT THIS IS A COMMAND FROM MS. HOLMES. THEY'RE STILL RELYING
02:23PM 15 ON IT BEING FAIR TO INFER THAT IT CAME FROM HER OR THAT IT
02:23PM 16 SOMEHOW WAS AUTHORIZED FROM HER, BUT AT THIS JUNCTURE THAT'S
02:23PM 17 JUST NOT SUFFICIENT TO SUPPORT AN ADMISSION OF RULE 404(B).

02:24PM 18 I THINK ANOTHER FACT THAT BEARS UPON WHY THESE AMBIGUOUS
02:24PM 19 EMAILS ARE A LITTLE BIT DANGEROUS IS THAT THE DOWNSTAIRS
02:24PM 20 LABORATORY, AND MY UNDERSTANDING OF IT, BOTH HAD AN R&D
02:24PM 21 COMPONENT AND A CLINICAL LABORATORY SEGMENT OF IT.

02:24PM 22 SO, I MEAN, THERE'S JUST A COMPLETELY INNOCUOUS REASON FOR
02:24PM 23 NOT BRINGING AN INSPECTOR THROUGH A PART OF THE LAB THAT, LIKE,
02:24PM 24 IS MORE COMPLICATED TO ACCESS UNLESS SHE ASKS TO SEE IT.

02:24PM 25 SO I'M NOT SAYING THAT THAT COMMAND CAME FROM MS. HOLMES.

02:24PM 1 THEY HAVE NOT PROFFERED EVIDENCE OF THAT.

02:24PM 2 MR. LEACH WAS TALKING ABOUT A STATEMENT FROM
02:24PM 3 ELENITOBA JOHNSON. TO MY KNOWLEDGE THAT'S NOT CONTAINED IN HER
02:24PM 4 GOVERNMENT INTERVIEW SO I'M CURIOUS AS TO WHAT THE PROVIDENCE
02:24PM 5 OF THAT IS.

02:25PM 6 BUT ULTIMATELY WE ARE LEFT IN SPECULATION LAND STILL. WE
02:25PM 7 HAVE NOT MOVED OFF OF IT. WE'RE JUST GOING TO BE ASKING THE
02:25PM 8 JURY TO READ MULTIPLE INFERENCES INTO AMBIGUOUS EMAILS THAT
02:25PM 9 JUST WON'T BEAR IT. AND THE GOVERNMENT CITES CASES -- A GOOD
02:25PM 10 CASE FROM THE EIGHTH CIRCUIT IN OUR REPLY, YOU KNOW, ABOUT
02:25PM 11 EXCLUDING KIND OF EVIDENCE THAT IS SO AMBIGUOUS THAT IT CAN BE
02:25PM 12 READ ANY WHICH NUMBER OF WAYS.

02:25PM 13 AT THAT POINT IT'S JUST NOT PROBATIVE OF ANYTHING ANYMORE,
02:25PM 14 AND WE SUBMIT THAT THAT'S WHAT THIS IS.

02:25PM 15 AND MR. LEACH IS CORRECT THAT I NEGLECTED TO ADDRESS THAT
02:25PM 16 WE ALSO MOVED TO EXCLUDE THE 2013 CDPH INSPECTION REPORT. IT'S
02:25PM 17 HEARSAY, AND SO ALL OF THE HEARSAY ARGUMENTS THAT WE'VE ALL
02:25PM 18 BEEN DISCUSSING ALL DAY, THEY APPLY EXACTLY THE SAME WAY.

02:25PM 19 HERE, THIS NONHEARSAY PURPOSE, WHEN MR. LEACH SAYS THAT
02:25PM 20 THE EXACT SAME ISSUES SHOW UP LATER ON, I JUST DON'T KNOW IF
02:26PM 21 THAT'S BORNE OUT BY THE EVIDENCE. I MEAN, THE CITATIONS IN THE
02:26PM 22 2013 CDP INSTRUCTION, AND IT'S ATTACHED TO THE MOTION, I MEAN,
02:26PM 23 THEY DO RELATE TO PROFICIENCY TESTING GENERALLY, BUT I THINK IT
02:26PM 24 WOULD BE HARD TO SAY THAT THEY ARE NOTICE OF KIND OF THE SAME
02:26PM 25 ISSUES. I JUST DON'T THINK THAT THE GOVERNMENT REALLY HAS

02:26PM 1 SUBSTANTIATED THAT AT THIS POINT.

02:26PM 2 IF ANYTHING, IF THE RAPID RECERTIFICATION OF THE
02:26PM 3 LABORATORY AFTER THE 2013 INSPECTION, WHICH HAPPENED WITHIN A
02:26PM 4 FEW MONTHS, IT'S NOTICED IN THE OPPOSITE DIRECTION. IT'S
02:26PM 5 NOTICED THAT A CDPH CAME IN, THEY SPOTTED SOME ISSUES, THESE
02:26PM 6 ARE THE THINGS THAT WE NEED TO DO TO IMPROVE, WE GOT THE GREEN
02:26PM 7 LIGHT, AND WE'RE GOING FORWARD.

02:26PM 8 SO, TO ME, IT'S ANOTHER PIECE OF AMBIGUOUS EVIDENCE THAT
02:26PM 9 IS BOTH HEARSAY AND NOT PROBATIVE OF ANYTHING AT ALL.

02:27PM 10 SO WALKING BACKWARDS IN TIME TO THE CMS OR TO THE LETTER,
02:27PM 11 AGAIN, A LOT OF MR. LEACH'S PRESENTATION KIND OF RELATED TO
02:27PM 12 OTHER EVIDENCE LIKE TEXT MESSAGES ABOUT PRAYING THAT AN
02:27PM 13 INSPECTION WOULD GO WELL.

02:27PM 14 WHAT I DIDN'T HEAR WAS REALLY ANY CONNECTION AGAIN TO
02:27PM 15 MS. HOLMES. IT WAS JUST SORT OF, WELL, SHE'S AROUND, SHE'S
02:27PM 16 AWARE THAT THERE'S AN INSPECTION, AND SO THIS STATEMENT MUST BE
02:27PM 17 ATTRIBUTABLE TO HER.

02:27PM 18 BUT OF COURSE SHE'S AWARE THAT THERE'S BEEN AN INSPECTION.
02:27PM 19 THAT'S NOT THE SAME QUESTION AS TO WHETHER OR NOT THE
02:27PM 20 GOVERNMENT HAS PROFFERED SUFFICIENT EVIDENCE TO MAKE A FINDING,
02:27PM 21 A THRESHOLD FINDING FOR ADMISSIBILITY UNDER RULE 404(B) FOR
02:27PM 22 THIS TYPE OF EVIDENCE.

02:27PM 23 AND THEN FINALLY, REGARDING MR. DHAWAN. AGAIN, SOME OF
02:28PM 24 THE EMAILS RELATING TO THE RETENTION OF MR. DHAWAN ARE ATTACHED
02:28PM 25 TO THE GOVERNMENT'S OPPOSITION. I WILL SAY THAT I'VE SPENT

02:28PM 1 TIME WITH THE DOCUMENTS, AND I DON'T READ THEM AS SAYING YOU
02:28PM 2 WILL HAVE TO DO NO WORK. THERE'S AN ESTIMATE FOR LIKE HOW MANY
02:28PM 3 HOURS THAT HE WOULD HAVE TO DEVOTE TO HIS RESPONSIBILITIES AT
02:28PM 4 THERANOS. AND HE ALSO WAS MAINTAINING A FULL-TIME PRACTICE IN
02:28PM 5 HIS OWN CLIA HIGH COMPLEXITY REGULATED LAB. SO I DON'T THINK
02:28PM 6 THAT THAT'S, LIKE, ANYTHING NEFARIOUS ABOUT THAT.

02:28PM 7 I THINK TO TAKE A STEP BACK, THE KIND OF COMPARISON THAT
02:28PM 8 MR. LEACH USES BETWEEN HE'S NOT THE SUPERSTAR, HE'S NOT
02:28PM 9 DAVID BOIES. I THINK WE'RE IN A UNIQUE POSITION HERE WHERE WE
02:28PM 10 CAN SEE THE KIND OF GROSSLY UNFAIRLY PREJUDICIAL LINK THAT THE
02:28PM 11 GOVERNMENT IS TRYING TO MAKE HERE BECAUSE THEY'RE JUST REALLY
02:28PM 12 LEADING WITH IT.

02:28PM 13 I JUST DON'T THINK THAT THAT EVIDENCE IS FAIRLY AT PLAY
02:28PM 14 HERE. I DON'T THINK THAT THAT ARGUMENT FOLLOWS FROM THE
02:29PM 15 RETENTION OF A PART-TIME LAB DIRECTOR WHO HAPPENS TO BE A
02:29PM 16 DERMATOLOGIST.

02:29PM 17 AND AGAIN, I DON'T THINK --

02:29PM 18 THE COURT: WELL, I GUESS THE INTERESTING PART IS
02:29PM 19 THAT IT'S MR. BALWANI'S DERMATOLOGIST, BUT THERE'S NOTHING
02:29PM 20 UNTOWARD ABOUT THAT YOU SUGGEST.

02:29PM 21 MR. LOOBY: RIGHT. THERE IS NOTHING UNTOWARD ABOUT
02:29PM 22 THAT.

02:29PM 23 THEIR LAB DIRECTOR, ADAM ROSENDORFF, LEFT. UNDER THE CLIA
02:29PM 24 REGULATIONS YOU NEED TO GET SOMEBODY IN LINE RIGHT AWAY.

02:29PM 25 THEY FIRST INQUIRED WITH DR. DHAWAN WHETHER OR NOT HE KNEW

02:29PM 1 ANYONE. AND THEN WHEN THEY LEARNED -- IT'S MOSTLY MR. BALWANI
02:29PM 2 IS DOING ALL OF THIS COMMUNICATION WITH DR. DHAWAN. IT TURNS
02:29PM 3 OUT THAT HE'S QUALIFIED. SO THEY SIGN HIM UP FOR A PART-TIME
02:29PM 4 POSITION AND A TEMPORARY POSITION.

02:29PM 5 THE IDEA IS NOT, OKAY, YOU'RE GOING TO BE OUR FULL-TIME
02:29PM 6 LAB DIRECTOR GOING FORWARD. IT'S MORE OF A STOPGAP. YOU KNOW
02:29PM 7 WHAT ELSE THEY DO? THEY HIRE LYNETTE SAWYER AT THE SAME TIME.

02:29PM 8 SO WHILE THERE ARE DISCUSSIONS, AND I WOULDN'T CALL THEM
02:30PM 9 HAGGLING OVER COMPENSATION, THERE WERE DISCUSSIONS OVER THE
02:30PM 10 MANNER IN WHICH DR. DHAWAN IS GOING TO BE COMPENSATED.

02:30PM 11 DR. SAWYER, ANOTHER UNCONTESTEDLY QUALIFIED LAB DIRECTOR,
02:30PM 12 IS REVIEWING LAB DOCUMENTATION AND SIGNING THEM.

02:30PM 13 THE COURT: SO MAYBE THIS ISN'T 404(B). MAYBE THIS
02:30PM 14 IS JUST FACT EVIDENCE.

02:30PM 15 WHAT'S THE HISTORY OF THE LAB DIRECTORS AT THERANOS?

02:30PM 16 WELL, WE HAD DR. ROSENDORFF. OKAY. HE LEFT.

02:30PM 17 WHO FOLLOWED HIM? THIS DOCTOR.

02:30PM 18 ALL RIGHT. WHAT WAS HIS, WHAT WAS HIS RELATION?

02:30PM 19 WELL, HE WAS A DERMATOLOGIST. HE WAS HIRED PART TIME
02:30PM 20 WHILE THEY COULD SECURE SOMEBODY ELSE.

02:30PM 21 OKAY. ANYTHING ELSE ABOUT HIM?

02:30PM 22 WELL, HE HAPPENED TO BE MR. BALWANI'S DERMATOLOGIST, AND
02:30PM 23 WE AGREED NOT TO HAVE HIM ON.

02:30PM 24 IS THAT JUST FACT EVIDENCE?

02:30PM 25 MR. LOOBY: RIGHT. AND I THINK THERE ARE CERTAIN

02:30PM 1 FACTS THAT COULD FAIRLY COME IN. I MEAN, IT WAS DISCLOSED AS
02:30PM 2 RULE 404(B). I THINK WITH THE GOVERNMENT'S PROPOSED USE OF IT
02:30PM 3 WITH THAT ANALOGY TO DAVID BOIES, I MEAN, THEN IT'S 404(B)
02:30PM 4 BECAUSE WE'RE TALKING ABOUT ANOTHER ACT. IT'S A BAD ACT THAT
02:31PM 5 THEY'RE ASKING TO DERIVE EVIDENCE OF INTENT FROM.

02:31PM 6 IT'S NOT LIKE A BASELINE FACT OF, OKAY, ROSENDORFF
02:31PM 7 DEPARTED, DHAWAN WAS NEXT, HE'S A DERMATOLOGIST. THAT IS NOT
02:31PM 8 -- THE GOVERNMENT HAS TOLD US HOW THEY'RE GOING TO USE THIS
02:31PM 9 EVIDENCE.

02:31PM 10 THE COURT: WELL, IF IT CAME IN JUST AS FACT
02:31PM 11 EVIDENCE, AS I SAID, WHAT IS THE HISTORY OF THE LAB
02:31PM 12 SUPERVISION? WOULD YOU ARGUE THAT THEY COULDN'T ARGUE THAT AS
02:31PM 13 INTENT TO SHOW INTENT, THE JURY COULD USE THIS TO CONSIDER,
02:31PM 14 WOW, LOOK WHAT THEY DID, THEY HIRED A DERMATOLOGIST, YOU COULD
02:31PM 15 CONSIDER THAT?

02:31PM 16 MR. LOOBY: RIGHT. I THINK THAT USE OF THE EVIDENCE
02:31PM 17 IS 404(B), AND I THINK ONCE THE 404(B) FRAMEWORK IS LAID OVER
02:31PM 18 IT, THE GOVERNMENT HAS TO KIND OF BE PRETTY EXPLICIT ABOUT LIKE
02:31PM 19 THE LINKAGE THAT THEY'RE GOING TO MAKE TO THE EVIDENCE IN THE
02:31PM 20 CASE AND TO INTENT. AND SO IT WOULD BE AN ORDER EXCLUDING THE
02:31PM 21 EVIDENCE UNDER 404(B) FOR THAT PURPOSE AND IN EFFECT IT WOULD
02:32PM 22 PRECLUDE THAT TYPE OF IMPROPER ARGUMENT IN EFFECT.

02:32PM 23 THE COURT: OKAY. ALL RIGHT. THANK YOU.

02:32PM 24 ANYTHING ELSE, MR. LEACH?

02:32PM 25 MR. LEACH: NO, YOUR HONOR.

02:32PM 1 THE COURT: ALL RIGHT. THANK YOU VERY MUCH. HAVE
02:32PM 2 WE EXHAUSTED THE MOTIONS FOR WEDNESDAY?

02:32PM 3 MS. SAHARIA: YES, WE HAVE, YOUR HONOR.

02:32PM 4 THE COURT: I THINK WE HAVE.

02:32PM 5 AND I FRAMED THAT QUESTION VERY CAREFULLY. I DID NOT ASK
02:32PM 6 IF ANYONE WAS EXHAUSTED. I NOTE THAT IT'S ABOUT 2:30. WE'RE
02:32PM 7 AHEAD OF SCHEDULE HERE. I JUST WONDER IF I COULD LOOK AT A
02:32PM 8 COUPLE OF TOMORROW'S, THURSDAYS.

02:32PM 9 I THINK THERE ARE A COUPLE THAT MIGHT BE -- AND I DON'T
02:32PM 10 MEAN TO CUT OFF DISCUSSION, BUT IT SEEMS LIKE THERE'S A COUPLE
02:32PM 11 OF THESE THAT WE MIGHT BE ABLE TO HANDLE WITH LITTLE
02:32PM 12 DISCUSSION.

02:32PM 13 IS THAT ALL RIGHT, MS. SAHARIA?

02:32PM 14 MS. SAHARIA: PERHAPS, YOUR HONOR. NOT ALL OF THE
02:32PM 15 TEAM MEMBERS WHO ARE PREPARED TO ARGUE THE MOTIONS ARE HERE
02:32PM 16 AND --

02:32PM 17 THE COURT: WELL, THE GOVERNMENT DOESN'T OBJECT TO
02:32PM 18 THAT.

02:32PM 19 MS. SAHARIA: AND WE DON'T HAVE ALL OF OUR NOTES,
02:33PM 20 BUT IF YOUR HONOR WANTS TO PERHAPS GIVE YOUR COMMENTS ON THE
02:33PM 21 MOTIONS, WE COULD -- THAT MIGHT SPEED ALONG HOW TO PROCEED.

02:33PM 22 THE COURT: SURE.

02:33PM 23 WELL, LET'S START WITH NUMBER 7, WHICH IS THE GOVERNMENT'S
02:33PM 24 MIL 9, AND THAT IS TO EXCLUDE SELF-SERVING HEARSAY STATEMENTS
02:33PM 25 MADE AND OFFERED BY THE DEFENDANT.

02:33PM 1 MS. SAHARIA: YES, YOUR HONOR.

02:33PM 2 THE COURT: AND THE NINTH CIRCUIT LAW IS THE ORTEGA
02:33PM 3 CASE SPEAKS TO THIS, 203 FED. 3D. THAT IS THE CASE THAT I WAS
02:33PM 4 GOING TO CALL OUT AND ASK IF THE PARTIES ARE AGREEING THAT
02:33PM 5 ORTEGA CONTROLS.

02:33PM 6 I DON'T KNOW IF THAT'S HELPFUL OR NOT. I DON'T KNOW IF
02:33PM 7 YOU ARE READY TO SPEAK TO THAT OR NOT.

02:33PM 8 MS. SAHARIA: I CAN SPEAK TO THAT. LET ME JUST USE
02:33PM 9 ONE MASK.

02:33PM 10 SO, YOUR HONOR, WITH RESPECT TO THE GOVERNMENT'S MOTION TO
02:33PM 11 EXCLUDE SELF-SERVING HEARSAY STATEMENTS, I THINK THE COURT
02:34PM 12 SHOULD DENY THAT MOTION FOR THE SAME REASON THAT THE COURT IN
02:34PM 13 THE YANG AND YAGI CASES DENIED THAT MOTION, WHICH IS, OF
02:34PM 14 COURSE, WE CANNOT ADMIT MS. HOLMES'S STATEMENTS FOR THEIR
02:34PM 15 TRUTH, BUT THERE ARE MANY OTHER PROPER REASONS WHY THEY MAY BE
02:34PM 16 ADMITTED.

02:34PM 17 THEY MAY BE ADMITTED FOR A NONHEARSAY PURPOSE, THE
02:34PM 18 STATEMENT MAY BE A VERBAL COMMAND TO ANOTHER EMPLOYEE, WHICH IS
02:34PM 19 NOT ADMITTED FOR THE TRUTH. THAT WOULD BE RELEVANT TO INTENT.
02:34PM 20 IT MAY BE ADMITTED AS A HEARSAY EXCEPTION AND A STATEMENT OF
02:34PM 21 MIND, FOR INSTANCE. SO THERE'S MANY PURPOSES FOR WHICH WE
02:34PM 22 MIGHT ADMIT THEM.

02:34PM 23 THE GOVERNMENT HAS NOT IDENTIFIED ANY STATEMENTS AT ISSUE
02:34PM 24 RIGHT NOW, SO THE MOTION IS ENTIRELY PREMATURE.

02:34PM 25 THERE WERE TWO OTHER KIND OF SUBSIDIARY ISSUES THAT THE

02:34PM 1 GOVERNMENT RAISES IN THAT MOTION WHICH I THINK ARE ALSO
02:34PM 2 COMPLETELY PREMATURE.

02:34PM 3 ONE IS PRIOR CONSISTENT STATEMENTS AND WHAT THE SCOPE OF
02:34PM 4 OUR ABILITY TO ADMIT PRIOR CONSISTENT STATEMENTS IS. I THINK
02:35PM 5 THAT'S JUST PREMATURE.

02:35PM 6 I WOULD JUST NOTE ONE ISSUE THERE, WHICH IS IN THE
02:35PM 7 GOVERNMENT'S MOTION IT CITES I THINK A 2008 CASE. I DON'T
02:35PM 8 REMEMBER THE NAME OF THE CASE. THAT WAS APPLYING THE PRIOR
02:35PM 9 STANDARD FOR PRIOR CONSISTENT STATEMENTS. THE RULES COMMITTEE
02:35PM 10 AMENDED THAT RULE IN 2014 TO BROADEN IT TO ALLOW A WIDER
02:35PM 11 VARIETY OF PRIOR CONSISTENT STATEMENTS TO BE ADMITTED FOR THEIR
02:35PM 12 TRUTH. SO I WOULD JUST NOTE THAT FOR THE RECORD THAT THAT IS
02:35PM 13 NOT THE RIGHT STANDARD THAT THEY HAVE CITED IN THEIR MOTIONS.

02:35PM 14 AND THEN ON THE RULE OF COMPLETENESS ISSUE, EVEN THE COURT
02:35PM 15 IN DASHNER, WHICH IS THE ONLY CASE THAT THEY RELIED ON, DENIED
02:35PM 16 THAT PART OF THE MOTION BECAUSE IT'S ENTIRELY PREMATURE.

02:35PM 17 THERE ARE THESE KIND OF HYPOTHETICAL ISSUES ADDRESSED BY
02:35PM 18 THE PARTIES ABOUT THE RULE OF COMPLETENESS AND WHETHER IT MIGHT
02:35PM 19 APPLY TO ORAL STATEMENTS AND HOW IT APPLIES WHEN THE STATEMENT
02:35PM 20 IS A HEARSAY STATEMENT.

02:35PM 21 IF YOUR HONOR WANTS US TO ADDRESS THOSE, WE CAN NOW, BUT I
02:36PM 22 THINK THEY'RE JUST COMPLETELY PREMATURE.

02:36PM 23 THE COURT: OKAY. THANK YOU.

02:36PM 24 WHO IS SPEAKING TO THIS MOTION?

02:36PM 25 MS. VOLKAR: KELLY VOLKAR ON BEHALF OF THE

02:36PM 1 UNITED STATES. IT'S A PLEASURE TO MEET YOU IN PERSON.

02:36PM 2 THE COURT: THANK YOU. LIKEWISE.

02:36PM 3 MS. VOLKAR: I APOLOGIZE I DON'T HAVE ALL OF MY
02:36PM 4 NOTES IN FRONT OF ME.

02:36PM 5 THE COURT: I DON'T MEAN TO CALL THIS OUT OF ORDER
02:36PM 6 AND TO PUT BOTH SIDES AT A DISADVANTAGE, BUT I JUST THOUGHT
02:36PM 7 THAT THE NINTH CIRCUIT LAW ON THIS IS SPELLED OUT CLEARLY I
02:36PM 8 THINK IN THE ORTEGA CASE. AND MY QUESTION WAS GOING TO BE CAN
02:36PM 9 WE GET AGREEMENT THAT THE PARTIES ARE GOING TO FOLLOW THE
02:36PM 10 NINTH CIRCUIT LAW AND THE ORTEGA CASE.

02:36PM 11 THE GENERAL, MS. SAHARIA, AS I'M CERTAIN YOU ARE AWARE
02:36PM 12 THAT THE GENERAL PROPOSITION IS THAT A DEFENDANT CANNOT GET IN
02:36PM 13 HIS OR HER EXCULPATORY OUT-OF-COURT STATEMENTS THAT MIGHT GO TO
02:36PM 14 AN ISSUE OF INTENT IN THE CASE.

02:36PM 15 MS. SAHARIA: WELL, I DON'T AGREE WITH THAT
02:37PM 16 FORMULATION BECAUSE THERE COULD BE EXCULPATORY STATEMENTS THAT
02:37PM 17 ARE NOT ADMITTED FOR THEIR TRUTH, RIGHT? THERE MAY BE A
02:37PM 18 STATEMENT OF MS. HOLMES'S STATE OF MIND WHICH WOULD COME IN
02:37PM 19 UNDER A HEARSAY EXCEPTION UNDER RULE 803 I BELIEVE.

02:37PM 20 THE COURT: OKAY.

02:37PM 21 MS. SAHARIA: THAT MAY BE EXCULPATORY, RIGHT? IT'S
02:37PM 22 A HELPFUL STATEMENT, BUT WE CAN ADMIT THAT BECAUSE IT'S NOT FOR
02:37PM 23 ITS TRUTH.

02:37PM 24 SO I TOTALLY AGREE THAT WE CANNOT ADMIT MS. HOLMES'S
02:37PM 25 STATEMENTS FOR THE TRUTH OF THE MATTER ASSERTED. THE POINT I

02:37PM 1 WAS MAKING BEFORE IS THAT THERE ARE MANY EXCEPTIONS UNDER THE
02:37PM 2 HEARSAY RULES THAT WOULD ALLOW US TO ADMIT MS. HOLMES'S
02:37PM 3 STATEMENTS.

02:37PM 4 THE COURT: TO ADVANCE THAT THEORY ANYHOW, RIGHT.

02:37PM 5 MS. SAHARIA: YES. AND JUST LIKE THE COURT SAID IN
02:37PM 6 YANG AND YAGI, YOU CAN'T DECIDE WHETHER ANY THE STATEMENTS
02:37PM 7 FALLS -- IS BEING ADMITTED FOR THE TRUTH OR IS BEING ADMITTED
02:37PM 8 FOR SOME OTHER PURPOSE UNTIL YOU ACTUALLY HAVE THAT STATEMENT
02:37PM 9 IN FRONT OF THE COURT.

02:37PM 10 THE COURT: OKAY. WELL, LET'S CONTINUE OUR
02:37PM 11 CONVERSATION ON THIS TOMORROW. I JUST POINT OUT THE ORTEGA
02:37PM 12 CASE FOR OUR DISCUSSION.

02:37PM 13 THE OTHER ONE THAT I THOUGHT WE WOULD HAVE DISCUSSION
02:37PM 14 ABOUT IS DOCUMENT 578, MS. HOLMES'S MOTION TO EXCLUDE CERTAIN
02:38PM 15 NEWS ARTICLES.

02:38PM 16 I THOUGHT I READ THERE WAS AN AGREEMENT EXCEPT FOR PARLOFF
02:38PM 17 AND TOPEL.

02:38PM 18 MS. SAHARIA: THAT'S MR. LOOBY'S MOTION. I THINK WE
02:38PM 19 MIGHT PREFER TO TABLE THAT UNTIL TOMORROW IF THAT'S OKAY WITH
02:38PM 20 YOUR HONOR.

02:38PM 21 THE COURT: SURE. SURE. OKAY. THOSE WERE THE TWO
02:38PM 22 THAT I THOUGHT WE COULD HANDLE WITH SOME EFFICIENCY TODAY, BUT
02:38PM 23 THAT'S FINE. WE'LL TALK ABOUT THOSE TOMORROW.

02:38PM 24 MS. SAHARIA: OKAY. THANK YOU.

02:38PM 25 THE COURT: ALL RIGHT. WHY DON'T WE END OUR DAY

02:38PM 1 TODAY, WHY DON'T WE END OUR DAY TODAY.

02:38PM 2 ANYTHING ELSE ANY OF THE PARTIES WANT TO RAISE TODAY OR

02:38PM 3 ANYTHING ELSE RELATED TO OUR TRIAL SCHEDULE?

02:38PM 4 MR. SCHENK: NO, YOUR HONOR. THANK YOU.

02:38PM 5 MS. SAHARIA: NO, YOUR HONOR.

02:38PM 6 THE COURT: OKAY. THANK YOU. HAVE A GOOD EVENING.

02:38PM 7 WE'LL SEE YOU TOMORROW.

02:38PM 8 TOMORROW AT 1:00 O'CLOCK, I THINK, MS. KRATZMANN? IS THAT

02:39PM 9 RIGHT?

02:39PM 10 THE CLERK: I BELIEVE IT WAS CALENDARED FOR 1:30.

02:39PM 11 WE CAN MOVE THAT UP TO 1:00 O'CLOCK.

02:39PM 12 THE COURT: LET'S DO THAT. I HAVE A CIVIL CALENDAR

02:39PM 13 AT 9:00 O'CLOCK AND ONE MATTER CAME OFF. LET'S JUST SAY 1:00

02:39PM 14 O'CLOCK OUT OF AN ABUNDANCE OF CAUTION.

02:39PM 15 MS. SAHARIA: SURE. THANK YOU.

02:39PM 16 MR. LEACH: TOO THANK YOU.

02:39PM 17 THE CLERK: COURT IS ADJOURNED FOR THE DAY. THE

02:39PM 18 CONFERENCE LINE SHALL TERMINATE.

02:39PM 19 (COURT CONCLUDED AT 2:39 P.M.)

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CERTIFICATE OF REPORTER

I, THE UNDERSIGNED OFFICIAL COURT REPORTER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER.

A handwritten signature in black ink that reads "Irene Rodriguez". The signature is written in a cursive, flowing style with a large, decorative flourish at the end of the last name.

IRENE RODRIGUEZ, CSR, RMR, CRR
CERTIFICATE NUMBER 8074

DATED: MAY 12, 2021